MEDICAL POLICY

POLICY TITLE	VAGUS NERVE AND IMPLANTABLE PERIPHERAL NERVE STIMULATORS
POLICY NUMBER	MP 1.034

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2026**

POLICY

Vagus Nerve Stimulator

Vagus nerve stimulation may be considered **medically necessary** as a treatment of medically refractory seizures.

Vagus nerve stimulation is considered **investigational** as a treatment of other conditions, including but not limited to depression, heart failure, upper-limb impairment due to stroke, essential tremors, headaches, fibromyalgia, tinnitus, and traumatic brain injury as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Transcutaneous (nonimplantable) vagus nerve stimulation devices are considered **investigational** for all indications as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Implantable Peripheral Nerve Stimulator

Peripheral nerve stimulation as a treatment for chronic pain is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure

Restorative neurostimulation therapy (ReActiv8) is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Medically refractory seizures are defined as seizures that occur despite therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse events of these drugs.

Spinal cord and dorsal root ganglion stimulation are covered in policy MP 1.069 and are not reviewed herein.

The Nalu Medical, Inc. and Neuspera Medical Inc. device indications state "trial devices are solely for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device."

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Cross-References:

MP 1.069 Spinal Cord Stimulation
MP 1.141 Peripheral Subcutaneous Field Stimulation (PSFS)
MP 2.092 Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation
MP 6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

DESCRIPTION/BACKGROUND

Vagus Nerve Stimulation

Vagus nerve stimulation (VNS) was initially investigated as a treatment alternative in patients with medically refractory partial-onset seizures for whom surgery is not recommended or for whom surgery has failed. Over time, the use of VNS has expanded to include generalized seizures, and it has been investigated for a range of other conditions.

While the mechanisms for the therapeutic effects of VNS are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. An electrical stimulus is applied to axons of the vagus nerve, which have their cell bodies in the nodose and junctional ganglia and synapse on the nucleus of the solitary tract in the brainstem. From the solitary tract nucleus, vagal afferent pathways project to multiple areas of the brain. VNS may also stimulate vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract.

Other types of implantable vagus nerve stimulators that are placed in contact with the trunks of the vagus nerve at the gastroesophageal junction are not addressed in this evidence review.

Regulatory Status

In Table 1 includes updates on the U.S. Food and Drug Administration (FDA) approval and clearance for VNS devices pertinent to this evidence review.

Table 1. FDA-Approved or -Cleared Vagus Nerve Stimulators

Device Name	Manufacturer	Cleared	PMA/510(k)	Indications
NeuroCybernetic Prosthesis (NCP®) / VNS Therapy®; Product Codes LYJ, MUZ	LivaNova (Cyberonics)	1997	P970003	Indicated or adjunctive treatment of adults and adolescents >12 y of age with medically refractory partial-onset seizures
		2005	P970003/ S50	Expanded indication for adjunctive long-term treatment of chronic or recurrent depression for patients ≥18 y of age experiencing a major depressive episode and have not had an adequate response to ≥4 adequate antidepressant treatments
		2017	P970003/ S207	Expanded indicated use as adjunctive therapy for seizures in patients ≥4 y of age with partial-onset seizures that are refractory to antiepileptic medications
gammaCore®; Product Codes PKR, QAK	ElectroCore	2017/2018	DEN150048/ K171306/ K173442	Indicated for acute treatment of pain associated with episodic cluster headache in adults using noninvasive VNS on the side of the neck
gammaCore-2®, gammaCore-Sapphire®; Product Code PKR	ElectroCore	2017/2018/ 2021	K172270/ K180538/ K182369/ K191830/ K203456/ K211856	Indicated for: Adjunctive use for the preventive treatment of cluster headache in adult patients. The acute treatment of pain associated with episodic cluster headache in adult patients. The acute treatment of pain associated with migraine headache in adult patients. The preventive treatment of migraine headache in adult patients.

FDA: Food and Drug Administration; PMA: premarket approval; VNS: vagus nerve stimulation

Peripheral Nerve Stimulation

Peripheral nerve stimulation (PNS) has been used to treat chronic pain. It is a system consisting of leads, electrodes, and a pulse transmitter that delivers electrical impulses to peripheral nerves. Leads are placed using ultrasound guidance and can be placed for temporary or permanent use in an outpatient procedure.

Peripheral Nerve Stimulation for Neuropathic Chronic Pain

Chronic, noncancer pain is responsible for a high burden of illness and can be defined as persistent pain that lasts for more than 3 months. Chronic pain of peripheral origin may be caused by damage to peripheral nerves impacting the upper and lower extremities.

Regulatory Status for PNS Devices for Neuropathic Chronic Pain

A number of PNS devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. These are listed in Table 2.

Two PNS devices by Stimwave Technologies Inc., the StimQ Peripheral Nerve Stimulator (PNS) System and the Receiver Kit, Trial Kit, Spare Lead Kit, Sterile Revision Kit, SWAG Kit, SWAG Accessory Kit, Charger Kit, were recalled in Sept 2020 for the product containing a non-functional component not referenced in product labeling.

Table 2. FDA-Cleared Peripheral Nerve Stimulation Devices (FDA Product Code: GZF)

Device Name	Manufacturer	Cleared	510(k)	Indications
Nalu Neurostimulation Kit (Integrated, 40 cm: Single 8/Dual 8), Nalu Neurostimulation Kit (Ported, 2 cm: Single 8/Dual 8), Dual 8 Ported Nalu Implantable Pulse Generator with 40 cm Kit, 40 cm/ 60 cm Trial/Extension Lead Kits, Patient Kits and miscellaneous replacement kits	Nalu Medical, Inc.	March 2019	K183579	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
IPG, integrated, 25/40 cm, single, tined, IPG, 2 cm, single 4, Lead (25/40 cm, 4, tined), Extension - 4	Nalu Medical, Inc.	Sept 2019	K191435	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole

				mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
StimRouter Neuromodulation System	Bioness, Inc.	Oct 2019, March 2020, Feb 2022	K190047, K200482, K211965	The StimRouter Neuromodualtion System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.
Stimulator, Stimulator Kit, External Transmitter, External Transmitter Kit	Micron Medical Corporation	Aug 2020	K200848	Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Moventis PNS is not intended to treat pain in the craniofacial region.
Neuspera Neurostimulation System (NNS)	Neuspera Medical, Inc.	Aug 2021	K202781	The Neuspera Neurostimulation System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole

				mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
Neuspera Nuity System	Neuspera Medical, Inc.	April 2023	K221303	The Neuspera Nuity™ System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
Freedom Peripheral Nerve Stimulator (PNS) System	Curonix, Inc	June 2024	K233162	The Freedom Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom Trial Lead Kit is only to be used in conjunction with the Freedom Neurostimulator Kit. The trial devices are solely used for a trial stimulation period (no longer than 30 days) to

				determine efficacy before recommendation for a permanent (long term) device.
SPRINT Peripheral Nerve Stimulation (PNS)	SPR Therapeutics, Inc	July 2018	K181422	The SPRINT PNS system is indicated for up to 60 days in the back and/or extremities for symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; symptomatic relief of post-traumatic pain; and symptomatic relief of post-operative pain. This system is not intended to treat pain in the craniofacial region.

Restorative Neurostimulation for Chronic Lower Back Pain Attributed to Multifidus Dysfunction

Restorative neuromodulation therapy (ReActiv8) uses an implanted device to deliver electrical stimulation to the nerves controlling the multifidus muscles of the lumbar spine. It is proposed that restorative neuromodulation reduces pain by triggering contractions of the multifidus muscles to restore neuromuscular control and help stabilize the spine. It is intended for individuals with intractable chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief.

Regulatory Status for Restorative Neurostimulation Devices

In 2020, the ReActiv8 (Mainstay Medical) was FDA approved through the Premarket Approval (PMA) process (PMA P190021) for individuals with intractable chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief. FDA Product Code: QLK

RATIONALE

Summary of Evidence

Vagus Nerve Stimulation

For individuals who have seizures refractory to medical treatment who receive VNS, the evidence includes RCTs and multiple observational studies. Relevant outcomes are symptoms,

change in disease status, and functional outcomes. The RCTs have reported significant reductions in seizure frequency for patients with partial-onset seizures. The uncontrolled studies have consistently reported large reductions in a broader range of seizure types in both adults and children. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-resistant depression who receive VNS, the evidence includes 2 RCTs evaluating the efficacy of implanted VNS for treatment-resistant depression compared to sham, 1 RCT comparing therapeutic to low-dose implanted VNS, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The sham controlled RCTs only reported short-term results and found no significant improvement in the primary outcome. The low-dose VNS controlled trial reported no statistically significant differences between the dose groups for change in depression symptom score from baseline. Other available studies are limited by small sample sizes, potential selection and confounding biases, and lack of a control group in the case series. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic heart failure who receive VNS, the evidence includes a systematic review including 4 RCTs and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Meta-analyses of the RCTs evaluating chronic heart failure found significant improvements in the New York Heart Association functional class, quality of life, 6-minute walk-test, and N-terminal-pro brain natriuretic peptide levels in patients treated with VNS compared to control. An analysis of the ANTHEM-HF uncontrolled trial evaluated longer-term outcomes of VNS use in chronic heart failure. They found that left ventricular (LV) ejection fraction improved by 18.7%, 19.3%, and 34.4% at 12, 24, and 36 months, respectively, with high-intensity VNS. Individuals with low-intensity VNS only had significant improvement in LV ejection fraction at 24 months (12.3%). The ANTHEM-HFpEF trial found improvements in New York Heart Association functional class, quality of life, and 6-minute walk test distances in patients with preserved ejection fraction and implanted VNS. Although this data is promising, a lack of a no-VNS comparator group precludes drawing conclusions based on findings from the uncontrolled studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have upper-limb impairment due to stroke who receive VNS, the evidence includes 3 pilot RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Two RCTs compared VNS plus rehabilitation to rehabilitation alone; 1 failed to show significant improvements for the VNS group on response and function outcomes, but the other, which had a larger patient population, found a significant difference in response and function outcomes. The other RCT compared VNS to sham and found that although VNS significantly improved response rate, there were 3 serious adverse events related to surgery. Longer-term follow-up studies are needed to evaluate long-term efficacy and safety. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other neurologic conditions (e.g., essential tremors, headache, fibromyalgia, tinnitus, autism) who receive VNS, the evidence includes case series. Relevant

outcomes are symptoms, change in disease status, and functional outcomes. Case series are insufficient to draw conclusions regarding efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transcutaneous Vagus Nerve Stimulation

For individuals with cluster headaches who receive transcutaneous VNS (tVNS; also referred to as noninvasive VNS [nVNS]) to prevent cluster headaches, the evidence includes 1 RCT. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. One RCT for prevention of cluster headaches showed a reduction in headache frequency but did not include a sham treatment group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cluster headaches who receive nVNS to treat acute cluster headache, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. The ACT1 and ACT2 RCTs compared nVNS to sham for treatment of acute cluster headaches in patients including both chronic and episodic cluster headache. In ACT1, there was no statistically significant difference in the overall population in the proportion of patients with pain score of 0 or 1 at 15 minutes into the first attack and no difference in the proportion of patients who were pain-free at 15 minutes in 50% or more of the attacks. In the episodic cluster headache subgroup (n=85) both outcomes were statistically significant favoring nVNS although the interaction p-value was not reported. In ACT2, the proportion of attacks with pain intensity score of 0 or 1 at 30 minutes was higher for nVNS in the overall population (43% vs. 28%, p=.05) while the proportion of attacks that were pain-free at 15 minutes was similar in the 2 treatment groups in the overall population (14% vs. 12%). However, a statistically significantly higher proportion of attacks in the episodic subgroup (n=27) were pain-free at 15 minutes in the nVNS group compared to sham (48% vs. 6%, p<.01). These studies suggest that people with episodic and chronic cluster headaches may respond differently to acute treatment with nVNS. Studies designed to focus on episodic cluster headache are needed. Quality of life and functional outcomes have not been reported. Treatment periods ranged from only 2 weeks to 1 month with extended open-label follow-up of up to 3 months. There are few adverse events of nVNS and they are mild and transient. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with migraine headaches who receive nVNS to treat acute migraine headaches, the evidence includes 1 RCT. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. One RCT has evaluated nVNS for acute treatment of migraine with nVNS in 248 patients with episodic migraine with/without aura. There was not a statistically significant difference in the primary outcome of the proportion of participants who were pain-free without using rescue medication at 120 minutes (30% vs. 20%; p=.07). However, the nVNS group had a higher proportion of patients with decrease in pain from moderate or severe to mild or no pain at 120 minutes (41% vs. 28%; p=.03) and a higher proportion of patients who were pain-free at 120 minutes for 50% or more of their attacks (32% vs. 18%; p=.02). There are few adverse events of nVNS and they are mild and transient. Quality of life and functional outcomes were not reported, and the double-blind treatment period was 4 weeks with

an additional 4 weeks of open-label treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic migraine headaches who receive nVNS to prevent migraine headaches, the evidence includes 3 RCTs. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. The EVENT RCT was a feasibility study of prevention of migraine that was not powered to detect differences in efficacy outcomes. It does not demonstrate the efficacy of nVNS for prevention of migraine. The PREMIUM RCT was a phase 3, multicenter, sham-controlled RCT including 341 randomized participants with a 12-week double-blind treatment period. The results of PREMIUM demonstrated that nVNS was not statistically significantly superior to sham with respect to the outcomes of reduction of at least 50% in migraine days from baseline to the last 4 weeks, reduction in number of migraine days from baseline to the last 4 weeks, or acute medication days. The PREMIUM II trial was a multicenter, sham-controlled RCT including 231 randomized participants with a 12-week double-blind treatment period. The trial was terminated early due to the COVID-19 pandemic and results were based on a modified intention-to-treat population that included 113 total participants. Results demonstrated that treatment with nVNS was not statistically significantly superior to sham with respect to the primary outcome of reduction in the number of migraine days per month during weeks 9 through 12, nor other outcomes such as mean change in the number of headache days or acute medication days. However, the percentage of patients with at least a 50% reduction in the number of migraine days was significantly greater in the nVNS group than in the sham group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other neurologic, psychiatric, or metabolic disorders (e.g., epilepsy, depression, schizophrenia, noncluster headache, impaired glucose tolerance, fibromyalgia, stroke) who receive tVNS, the evidence includes RCTs, systematic reviews of these RCTs, and case series for some of the conditions. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs are all small and have various methodologic problems. None showed definitive efficacy of tVNS in improving patient outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Peripheral Nerve Stimulators for Neuropathic Pain

For individuals who have peripheral, neuropathic, chronic pain who receive peripheral nerve stimulation (PNS), the evidence includes several randomized controlled trials (RCTs). Relevant outcomes are symptoms, medication use, and quality of life. Statistically significant differences in responder rates were reported in the RCTs ranging from 38% to 88% in the treatment groups and 0% to 24% in the control groups. Overall limitations of the current evidence includes small sample sizes, heterogeneous patient populations, high attrition rates, and lack of long-term follow-up data. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data are necessary to assess the efficacy and durability of PNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Restorative Neurostimulation Therapy

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For individuals who have chronic pain conditions including low back pain who receive restorative neurostimulation therapy (ReActiv8), the evidence includes 1 sham-controlled RCT (N = 204), 1 open-label RCT (N=203), 1 prospective single-arm trial (N = 53), and a case series (N = 44). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the sham-controlled RCT, there was no difference between groups on the primary endpoint of treatment response at 120 days, defined as the composite of 30% or greater reduction in VAS and no increase in pain medications (57.1% intervention vs 46.6% sham; p =.1377). Prespecified secondary analyses of primary outcome data favored the intervention group, but clinical significance is unclear. An uncontrolled follow-up phase of the RCT reported continued improvement in pain scores through 3 years but results are at high risk of bias due to lack of a control group and high attrition. The open-label RCT showed statistically significant improvements in the treatment arm compared to the control arm in the primary and secondary outcomes. However, limitations included lack of blinding, imbalance in baseline depression between treatment and control arms, and greater clinical contact than standard management protocols in the treatment arm. Nonrandomized studies are limited by lack of blinding, no sham control, high attrition. and small sample sizes. Additional evidence from longer-term sham controlled RCTs is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

DEFINITIONS

EPILEPSY is a group of neurologic disorders characterized by recurrent episodes of convulsive seizures, sensory disturbances, abnormal behavior, loss of consciousness, or all of these. Common to all types of epilepsy is an uncontrolled electrical discharge from the nerve cells of the cerebral cortex.

PARTIAL ONSET SEIZURES refers to seizures that have a discrete focal onset. There are three subtypes of partial onset seizures:

- Simple partial seizures: these do not involve alteration of consciousness but may have observable motor components or may solely be a subjective sensory or emotional phenomenon.
- Complex partial seizures: these are partial-onset seizures that involve an alteration of consciousness.
- Complex partial seizures, secondarily generalized: These are partial-onset seizures that progress to involve both sides of the brain and result in a complete loss of consciousness.

VAGUS NERVE refers to either one of the longest pair of cranial nerves mainly responsible for parasympathetic control over the heart and many other internal organs, including thoracic and abdominal viscera.

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DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered: Non-implantable Vagus Nerve Stimulator and Implantable VNS for conditions other than medically refractory seizures:

Procedure Codes							
E0735	0908T	0909T	0910T	0911T	0912T	64999	

Investigational; therefore, not covered: Implantable Peripheral Nerve Stimulator

Procedure Codes							
64555	64575	64585	64590	64595	64596	64597	64598
64999	A4438						

Covered when medically necessary: Vagus nerve stimulator to treat medically refractory seizures:

Procedure Codes							
61885	61886	64553	64568	64569	64570	95976	95977

ICD-10-CM Diagnosis Codes	Description
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus

ICD-10-CM Diagnosis Codes	Description
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
G40.211	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
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.803	Other epilepsy, intractable, with status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus
G40.843	KCNQ2-related epilepsy, intractable, with status epilepticus
G40.844	KCNQ2-related epilepsy, intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus

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ICD-10-CM Diagnosis Codes	Description
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus
G40.C11	Lafora progressive myoclonus epilepsy, intractable, with status epilepticus
G40.C19	Lafora progressive myoclonus epilepsy, intractable, without status epilepticus
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord)
Z45.49	Encounter for adjustment and management of other implanted nervous system device
Z46.2	Encounter for fitting and adjustment of other devices related to nervous system and special senses

Covered when Medically Necessary when billed with an allowed surgery:

Procedure Codes							
C1767	C1778	C1816	C1820	C1827	C1883	C1897	L8678
L8679	L8680	L8681	L8682	L8683	L8685	L8686	L8687
L8688	L8689	L8695	95970	95971	95972		

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POLICY TITLE	VAGUS NERVE AND IMPLANTABLE PERIPHERAL NERVE STIMULATORS
POLICY NUMBER	MP 1.034

POLICY HISTORY

MP 1.034	**03/25/2020 Consensus Review.** Policy statement unchanged. Variations, definitions, and references updated. Coding reviewed.
	03/19/2021 Administrative Update. Added new HCPCS code K1020.
	04/01/2021 Minor Review. Added new CPT codes: 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T. Added HCPC code C1823, added ICD-10 code G47.31, Added to policy statement. References updated and added. Description/Background and Rationale updated.
	06/14/2022 Consensus Review. No change to policy statement. References, background, and rationale updated. Coding reviewed.
	03/16/2023 Administrative Update. Added new HCPCS Code L8678.
	07/18/2023 Consensus Review. No change to policy statement. New references.
	10/11/2023 Minor Review. Added NMN statement for restorative neurostimulation therapy (ReActiv8 device). Updated background, rationale, and references. Moved K1020 to correct coding table based on our policy statement.
	12/12/2023 Administrative Update. New Code Review: 33276-33288 replacing 0424T-0436T. E0735 replacing K1020. Adding 64596-64598 and 93150-93153.
	03/15/2024 Administrative Update. Added New Code A4438. Effective 04/01/2024.
	08/15/2024 Administrative Update. Added new ICD-10 codes. Effective 10/01/2024.
	08/29/2024 Minor Review. Title change. Minor editorial refinements to VNS statements; no change to intent. Added statement to VNS that transcutaneous/non-implantable is INV. Implantable peripheral nerve stimulators are now INV. ReActiv8 went from NMN to INV. Phrenic Nerve Stimulation has been removed from this policy; phrenic nerve stimulation for CSA has been moved to MP 1.128. Added policy guidelines. Updated cross references, background, rationale, definitions, and references. Placed codes used for more than one indication into coding table titled “Covered when Medically Necessary when billed with an allowed surgery”.
	12/13/2024 Administrative Update. Added 0908T-0912T as part of New Code Update. Eff date 01/01/2025
	06/26/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	09/22/2025 Consensus Review. Updated policy guidelines, cross-references, background, rationale, and references. Added 64999 and C1827 to coding tables.

MEDICAL POLICY

POLICY TITLE	VAGUS NERVE AND IMPLANTABLE PERIPHERAL NERVE STIMULATORS
POLICY NUMBER	MP 1.034

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