

MEDICAL POLICY

POLICY TITLE	IMPLANTABLE ELECTRICAL NERVE STIMULATORS (VAGUS, PHRENIC NERVE AND PERIPHERAL NERVE STIMULATORS)
POLICY NUMBER	MP 1.034

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	1/1/2025

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I. POLICY

Vagus Nerve Stimulator

The vagus nerve stimulator may be considered **medically necessary** as a treatment of medically refractory seizures.

The use of a vagus nerve stimulator is considered **investigational** for treatment of other conditions including but not limited to depression, heart failure, upper-limb impairment due to stroke, essential tremor, 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.

Peripheral Nerve Stimulator

Implantation of a peripheral nerve stimulator may be considered **medically necessary** to alleviate chronic intractable pain.

Restorative neurostimulation therapy (ReActiv8) is considered **not medically necessary** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Phrenic Nerve Stimulator

Implantation of a phrenic nerve stimulator may be considered **medically necessary** for the treatment of patients with partial or complete respiratory insufficiency.

Implantation of an autonomic nerve stimulator other than phrenic nerve is considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Implantation of a phrenic nerve stimulator for conditions other than partial or complete respiratory insufficiency is considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The use of phrenic nerve stimulation for central sleep apnea is considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 1.042 Deep Brain Stimulation

MP 1.069 Spinal Cord Stimulation

MP 1.141 Peripheral Subcutaneous Field Stimulation (PSFS)

MP 6.020 Transcutaneous Electrical Nerve Stimulation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI 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> .

III. DESCRIPTION/BACKGROUND

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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.

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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®)	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®	ElectroCore	2017	K171306	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®	ElectroCore	2017/2018	K172270/ K180538/ K182369/ K191830	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.

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				<p>The acute treatment of pain associated with migraine headache in adult patients.</p> <p>The preventive treatment of migraine headache in adult patients.</p>
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FDA: Food and Drug Administration; PMA: premarket approval; VNS: vagus nerve stimulation

Peripheral Nerve Stimulator

Peripheral nerve stimulation involves the implantation of electrodes around a selected peripheral nerve and is used to treat chronic intractable pain. The stimulating electrode is connected by an insulated lead to a receiver unit that is inserted subcutaneously at a depth not greater than half an inch. Sciatic and ulnar nerves are common sites for implantation. Stimulation of the nerve is created by a generator that is connected to an antenna that is attached to the skin surface over the receiver unit.

Restorative neurostimulation is an emerging therapy aimed at reducing pain and disability from chronic mechanical low back pain (LBP) by improving the function of muscles that stabilize the lumbar spine. Currently, the only FDA approved restorative neurostimulation therapy is the ReActiv8 device. While it may meet the definition of an implanted peripheral nerve stimulator, compared to traditional peripheral nerve stimulation devices, the ReActive8 uses a different mechanism of action to exert its clinical effect. Furthermore, this device is not appropriate for use in patients who have pain of predominantly neuropathic origin.

REGULATORY STATUS

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

Phrenic Nerve Stimulator

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

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Currently, there is one phrenic nerve stimulation device approved by the U.S. Food and Drug Administration (FDA) for CSA, the remede System (Respicardia, Inc.). A cardiologist implants the battery powered device under the skin in the right or left pectoral region using local anesthesia. The device has two leads, one to stimulate a phrenic nerve (either the left pericardiophrenic or right brachiocephalic vein) and one to sense breathing. The device runs on an algorithm that activates automatically at night when the patient is in a sleeping position and suspends therapy when the patient sits up. Patient-specific changes in programming can be conducted externally by a programmer.

However, an implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm. Moreover, nerve injury may occur during the surgical procedure and if sufficient injury has incurred, the device will not prove useful to the patient. Consequently, it is possible for such a device to be indicated for a patient but, due to injury sustained during implant, fail to assist the patient, resulting in a return to the use of mechanical ventilation.

Central Sleep Apnea

Central sleep apnea (CSA) is characterized by repetitive cessation or decrease in both airflow and ventilatory effort during sleep. Central sleep apnea may be idiopathic or secondary (associated with a medical condition such as congestive heart failure, drugs, or high-altitude breathing). Apneas associated with Cheyne-Stokes respiration are common among patients with heart failure (HF) or who have had strokes, and account for about half of the population with CSA. Central sleep apnea is less common than obstructive sleep apnea. Based on analyses of a large community-based cohort of participants 40 years of age and older in the Sleep Heart Health Study, the estimated prevalence of CSA and obstructive sleep apnea are 0.9% and 47.6%, respectively.¹ Risk factors for CSA include age (>65 years), male gender, history of HF, history of stroke, other medical conditions (acromegaly, renal failure, atrial fibrillation, low cervical tetraplegia, and primary mitochondrial diseases), and opioid use. Individuals with CSA have difficulty maintaining sleep and therefore experience excessive daytime sleepiness, poor concentration, and morning headaches, and are at higher risk for accidents and injuries.

Treatment

The goal of treatment is to normalize sleep-related breathing patterns. Because most cases of CSA are secondary to an underlying condition, central nervous system pathology, or medication side effects, treatment of the underlying condition or removal of the medication may improve CSA. Treatment recommendations differ depending on the classification of CSA as either hyperventilation-related (most common, including primary CSA and those relating to HF or high-altitude breathing) or hypoventilation-related (less common, relating to central nervous system diseases or use of nervous system suppressing drugs such as opioids).

For patients with hyperventilation-related CSA, continuous positive airway pressure (CPAP) is considered first-line therapy. Due to CPAP discomfort, patient compliance may become an issue. Supplemental oxygen during sleep may be considered for patients experiencing hypoxia during sleep or who cannot tolerate CPAP. Patients with CSA due to HF with an ejection fraction >45%,

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and who are not responding with CPAP and oxygen therapy, may consider bilevel positive airway pressure or adaptive servo-ventilation (ASV) as second-line therapy. Bilevel positive airway pressure devices have 2 pressure settings, 1 for inhalation and 1 for exhalation. Adaptive servo-ventilation uses both inspiratory and expiratory pressure and titrates the pressure to maintain adequate air movement. However, a clinical trial reported increased cardiovascular mortality with ASV in patients with CSA due to HF and with an ejection fraction <45%, 2, and therefore, ASV is not recommended for this group.

For patients with hypoventilation-related CSA, first-line therapy is bilevel positive airway pressure.

Pharmacologic therapy with a respiratory stimulant may be recommended to patients with hyper- or hypoventilation CSA who do not benefit from positive airway pressure devices, though close monitoring is necessary due to the potential for adverse effects such as rapid heart rate, high blood pressure, and panic attacks.

Phrenic Nerve Stimulation

Several phrenic nerve stimulation systems are available for patients who are ventilator dependent. These systems stimulate the phrenic nerve in the chest, which sends signals to the diaphragm to restore a normal breathing pattern. Currently, there is 1 phrenic nerve stimulation device approved by the U.S. Food and Drug Administration (FDA) for CSA, the remedē System (Zoll Medical). A cardiologist implants the battery-powered device under the skin in the right or left pectoral region using local anesthesia. The device has 2 leads, 1 to stimulate a phrenic nerve (either the left pericardiophrenic or right brachiocephalic vein) and 1 to sense breathing. The device runs on an algorithm that activates automatically at night when the patient is in a sleeping position and suspends therapy when the patient sits up. Patient-specific changes in programming can be conducted externally by a programmer.

Regulatory Status

In October 2017, the remedē System (Respicardia, Inc [now Zoll Medical]; Minnetonka, MN) was approved by the FDA through the premarket approval application process. The approved indication is for the treatment of moderate to severe CSA in adults. Follow-up will continue for 5 years in the post-approval study. FDA product code: PSR

IV. RATIONALE

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Summary of Evidence

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

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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 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%). 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 tremor, 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

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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 episodic cluster headaches who receive transcutaneous VNS, the evidence includes three RCTs. One RCT for a cluster headache showed a reduction in headache frequency but did not include a sham treatment group. Two randomized, double-blind, sham-controlled studies showed efficacy of achieving pain-free status within 15 minutes of treatment with noninvasive VNS in patients with episodic cluster headaches but not in patients with chronic cluster headaches. The RCTs for episodic cluster headaches are promising; however, additional studies with larger relevant populations are required to establish the treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic, psychiatric, or metabolic disorders (e.g., epilepsy, depression, schizophrenia, non-cluster headache, impaired glucose tolerance) who receive transcutaneous VNS, the evidence includes 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 transcutaneous VNS in improving patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Restorative Neurostimulation Therapy

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 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 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. 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.

Phrenic Nerve Stimulation for Central Sleep Apnea

For individuals with CSA who receive phrenic nerve stimulation, the evidence includes one randomized controlled trial (RCT) and observational studies. Relevant outcomes are change in disease status, functional outcomes, and quality of life. The RCT compared the use of phrenic nerve stimulation to no treatment among patients with CSA of various etiologies. All patients received implantation of the phrenic nerve stimulation system, with activation of the system after 1 month in the intervention group and activation after 6 months in the control group. Activation is delayed one month after implantation to allow for lead healing. At 6 months follow-up, the

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patients with the activated device experienced significant improvements in several sleep metrics and quality of life measures. At 12 months follow-up, patients in the activated device arm showed sustained significant improvements from baseline in sleep metrics and quality of life. A subgroup analysis of patients with heart failure combined 6- and 12-month data from patients in the intervention group and 12- and 18-month data from the control group. Results from this subgroup analyses showed significant improvements in sleep metrics and quality of life at 12 months compared with baseline. Results from observational studies supported the results of the RCT. An invasive procedure would typically be considered only if non-surgical treatments had failed, but there is limited data in which phrenic nerve stimulation was evaluated in patients who had failed the current standard of care, positive airway pressure, or respiratory stimulant medication. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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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.

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.

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.

PHRENIC NERVE is a nerve that arises mainly from the fourth cervical nerve and is primarily the motor nerve of the diaphragm but also sends sensory fibers to the pericardium.

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.

VISCERAL AFFERENT FIBERS are the nerve fibers of the visceral nervous system that receive stimuli, carry impulses toward the central nervous system, and share the sensory ganglia of the cerebrospinal nerves with the somatic sensory fibers.

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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, for treatment of headaches:

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

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

Procedure Codes							
L8678	61885	61886	64553	64568	64569	64570	95970
95976	95977						

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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
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
G40.911	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.C01	Lafora progressive myoclonus epilepsy, not intractable, with status epilepticus
G40.C09	Lafora progressive myoclonus epilepsy, not 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; Peripheral nerve stimulator to alleviate chronic intractable pain:

Procedure Codes							
64555	64575	64585	64590	64595	64596	64597	64598
A4438							

ICD-10-CM Diagnosis Codes	Description
G89.0	Central pain syndrome
G89.21	Chronic pain due to trauma
G89.22	Chronic post-thoracotomy pain
G89.28	Other chronic postprocedural pain
G89.29	Other chronic pain
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
G90.50	Complex regional pain syndrome I, unspecified

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ICD-10-CM Diagnosis Codes	Description
G90.59	Complex regional pain syndrome I of other specified site
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

Covered when medically necessary: Phrenic nerve stimulator to treat patients with partial or complete respiratory insufficiency:

Procedure Codes							
64575	64580	64585	64590	64595			

ICD-10-CM Diagnosis Codes	Description
J80	Acute respiratory distress syndrome
J95.1	Acute pulmonary insufficiency following thoracic surgery
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J95.3	Chronic pulmonary insufficiency following surgery
J95.82	Postprocedural respiratory failure
J96.0	Acute respiratory failure
J96.1	Chronic respiratory failure
J96.2	Acute and chronic respiratory failure
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

Investigational; therefore, not covered: Phrenic Nerve Stimulation for Central Sleep Apnea

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Procedure Codes							
33276	33277	33278	33279	33280	33281	33287	33288
93150	93151	93152	93153	C1823			

ICD-10-CM Diagnosis Codes	Description
G47.31	Primary central sleep apnea

Covered when Medically Necessary when billed with an allowed surgery:

Procedure Codes							
C1767	C1778	C1816	C1829	C1883	C1897	L8679	L8680
L8681	L8682	L8683	L8685	L8686	L8687	L8688	L8689
L8695							

IX. REFERENCES

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Vagus Nerve Stimulation

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POLICY TITLE	IMPLANTABLE ELECTRICAL NERVE STIMULATORS (VAGUS, PHRENIC NERVE AND PERIPHERAL NERVE STIMULATORS)
POLICY NUMBER	MP 1.034

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14. Centers for Medicare and Medicaid Services. Local Coverage Determination: Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (A57548) 2019
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 18. Blue Cross Blue Shield Association Medical Policy Reference Manual 2.02.33 Phrenic Nerve Stimulation for Central Sleep Apnea, June 2023.

X. POLICY HISTORY

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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.

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	03/15/2024 Administrative Update. Added New Code A4438. Effective 4/1/2024.
	12/11/2024 Administrative Update. Added codes 0908T-0912T. Effective 1/1/2025.

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