

Implantable Peripheral Nerve Stimulation Devices

Policy # 00473

Original Effective Date: 07/15/2015

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Electrical Nerve Stimulation Devices is addressed separately in medical policy 00142.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Note: Occipital Nerve Stimulation is addressed separately in medical policy 00253.

Note: Spinal Cord and Dorsal Root Ganglion Stimulators is addressed separately in medical policy 00260.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers implantable peripheral nerve stimulation to be **investigational*** for the treatment of acute and chronic pain including, but not limited for the following indications:

- Chronic pain of peripheral nerve origin, e.g., peripheral neuropathic (extremity) pain;
- Post-amputation/phantom-limb pain;
- Post-surgical pain;
- Axial/low back pain (including persistent spinal pain syndrome);
- Craniofacial pain.

Note: Examples of implantable peripheral nerve stimulation devices (not limited to): Nalu Neurostimulation System, ReActiv8 Implantable Neurostimulation System, SPRINT[®] PNS System, StimQ PNS System, StimRouter[®] PNS System, Neuspera Neurostimulation System, Neuspera Nuity System.

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Background/Overview

This document addresses implantable peripheral nerve stimulation devices as a treatment for pain. These devices are temporarily implanted and provide direct electrical stimulation to peripheral nerves.

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. Peripheral nerve stimulation has been evaluated across a range of chronic pain conditions amenable to stimulation at a peripheral nerve target, including peripheral neuropathic pain of the extremities, post-amputation and phantom-limb pain, persistent post-surgical pain, axial/low back pain (including persistent spinal pain syndrome), and craniofacial pain. The clinical context and therapy rationale specific to each indication are described in the corresponding sections of the review below.

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

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

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 1.

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.

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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Table 1. FDA-Cleared Peripheral Nerve Stimulation Devices (FDA Product Codes: GZF, NHI)

Device Name	Manufacturer	Cleared	510(k)	Indications
SPRINT Peripheral Nerve Stimulation System	SPR Therapeutics, Inc.	July 2018	K181422	The SPRINT Peripheral Nerve Stimulation (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; Symptomatic relief of post-operative pain. The SPRINT PNS System is not intended to treat pain in the craniofacial region.
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.

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StimRouter Neuromodulation System	Bioness, Inc.	Oct 2019, March 2020, Feb 2022	K190047, K200482, K211965	The StimRouter Neuromodulation 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 (eg, 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 ^{TM†} 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

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				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, LLC	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.
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/60 cm Trial/Extension Lead Kits, Patient Kits and Miscellaneous Replacement Kits	Nalu Medical, Inc.	Aug 2024	K232415	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. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

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TalisMann Neuromodulation System	Bioventus, LLC	July 2025	K243678	The TalisMann Neuromodulation 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 (eg, medications). The TalisMann Neuromodulation System is not intended to treat pain in the craniofacial region.
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PNS: peripheral nerve stimulation.

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Peripheral nerve stimulation (PNS) is a percutaneous 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.

ReActiv8 is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

Summary of Evidence

For individuals who have peripheral neuropathic chronic pain who receive peripheral nerve stimulation (PNS), the evidence includes two RCTs and several systematic reviews. Relevant outcomes are symptoms, medication use, and quality of life. Both RCTs favored active PNS: responder rates were significantly higher with PNS than with the comparator (38% vs. 10% using a $\geq 30\%$ pain-reduction threshold in one trial and 84% vs. 3% using a $\geq 50\%$ threshold in the other), with concordant improvements in quality of life and the Patient Global Impression of Change and response sustained through 12 months in the larger trial; no serious adverse events were reported. The systematic reviews were directionally consistent but graded the certainty of evidence as low to very low, reflecting predominantly observational source data and substantial heterogeneity. Limitations include small sample sizes, heterogeneous patient populations, differing responder

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definitions across trials, high attrition after randomization, and an open-label, usual-care comparator with a short (3-month) controlled period before crossover in the pivotal trial. Additional evidence from adequately powered, blinded RCTs with longer durations of comparative data is 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.

For individuals who have chronic post-amputation pain (including residual-limb and phantom-limb pain) who receive temporary (60-day) peripheral nerve stimulation (PNS), the evidence includes a single small, sham-controlled RCT with 12-month follow-up. Relevant outcomes are symptoms, medication use, and quality of life. Responder rates ($\geq 50\%$ pain reduction) were significantly higher with active PNS than with sham (58% to 67% vs. 14%), and the between-group difference persisted at 12 months; no serious adverse events were reported. Limitations include a very small sample size, a partial-crossover design that limited the duration of time-matched placebo comparison, and optional, inconsistently applied lead replacement at crossover. Additional evidence from adequately powered RCTs with longer time-matched comparative follow-up is 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.

For individuals who have persistent post-surgical pain who receive temporary (14- to 60-day) PNS, the evidence includes two small, sham-controlled RCTs. Relevant outcomes are symptoms, medication use, function, and quality of life. Both trials favored active PNS, with significantly lower opioid consumption and pain scores in one, and a higher $\geq 50\%$ pain-relief responder rate (60% vs. 24%) with concordant functional and quality-of-life gains in the other; no serious adverse events were reported. Limitations include small sample sizes, short controlled treatment durations, high loss to follow-up, early termination of one trial owing to COVID-19-related enrollment challenges, and heterogeneous surgical populations. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data is 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.

For individuals who have chronic axial low back pain, including persistent spinal pain syndrome, who receive temporary or permanent PNS, the evidence includes two RCTs: one large, pragmatic trial with an open-label usual-care comparator and one small, sham-controlled trial. Relevant outcomes are symptoms, medication use, disability, and quality of life. Responder rates ($\geq 50\%$ pain reduction) were significantly higher with PNS than with the comparator (55% vs. 26% and 63% vs. 16%), with concordant improvements in disability, PGIC, and quality of life. Limitations include the open-label, unblinded comparator in the larger trial; the very small sample size and short (1-month) blinded window in the sham-controlled trial, with long-term data drawn from its uncontrolled active arm; and heterogeneity in device modality and stimulation target. Additional evidence from adequately powered, blinded RCTs with longer comparative follow-up is 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.

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For individuals who have refractory chronic craniofacial neuropathic pain who receive permanent PNS, the evidence includes a single RCT that used an enriched-enrollment, randomized-withdrawal design. Relevant outcomes are symptoms, medication use, and quality of life. Among early responders randomized to continued stimulation versus device deactivation, 69% versus 11% achieved $\geq 50\%$ pain relief at 3 months (60% vs. 10% in the intention-to-treat analysis), with concordant secondary gains and no serious adverse events. Limitations include the single-trial evidence base, an enriched-enrollment design that restricts randomization to early responders and may overstate the effect relative to an all-comers population, and a short (3-month) blinded withdrawal window. Additional evidence from independent RCTs with all-comers enrollment and longer comparative follow-up is 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.

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.

Supplemental Information/Definitions

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published consensus clinical guidelines for the use of implantable peripheral nerve stimulation in the treatment of chronic pain based on a review of the literature through March 2021. Relevant recommendations for best practices pertinent to this review are listed below in Table 2.

Table 2. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
<i>Upper Extremities</i>		
PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain.	I	B
PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief.	II-2	B
<i>Lower Extremities</i>		
PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief.	I	B
PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief.	I	B

DOR: degree of recommendation; LOE: level of evidence; PNS: peripheral nerve stimulation.

American Society of Pain and Neuroscience: 60-Day Peripheral Nerve Stimulation (NEURON Living Guideline)

In 2025, the American Society of Pain and Neuroscience (ASPN) published a NEURON living-guideline addressing the use of 60-day peripheral nerve stimulation therapy. The guidance seeks to clarify the distinctions among trial stimulation, permanent implantation, and the fixed 60-day treatment approach, and offers best-practice consensus points derived from an evidence-graded assessment combined with expert clinical opinion. This was an expert consensus rather than a de novo systematic review.

American Society of Pain and Neuroscience: Peripheral Nerve Stimulation (NEURON Project)

In 2025, the ASPN published a NEURON consensus guideline on the use of peripheral nerve stimulation for chronic pain and neurological conditions, updating and expanding its prior review of the evidence and providing consensus best-practice recommendations across anatomic targets and

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indications. This document reflects evidence-graded expert consensus rather than a de novo systematic review.

National Institute for Health and Care Excellence

In September 2022, NICE published guidance on neurostimulation of lumbar muscles with the ReActiv8 system for refractory non-specific chronic low back pain.

The guidance was based on a rapid review conducted in July 2021 and included the following statements:

- "Evidence on the efficacy and safety of neurostimulation of lumbar muscles for refractory non-specific chronic low back pain is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."
- "Further research should include suitably powered randomised controlled trials comparing the procedure with current best practice with appropriate duration. It should report details of patient selection and long-term outcomes."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently has the following national coverage policy on PNS.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Tables 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05287373 ^a	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain	89 (actual)	Sept 2026
NCT05870124 ^a	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain (COMFORT 2)	185 (actual)	Dec 2027
NCT06741579	Mechanisms of Stimulation for Pain Alleviation (M-SPA): Phase 3 randomized controlled trial of peripheral nerve stimulation (Nalu or SPRINT) plus conventional medical	148 (anticipated)	Nov 2028

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	management versus conventional medical management alone for chronic neuropathic low back and leg pain		
NCT03877653a	Double-Blinded Randomized Controlled Trial of Knee Pain Utilizing Sub-Threshold Peripheral Nerve Stimulation (Freedom-1): Freedom (Curonix) PNS System for osteoarthritic knee pain	100 (anticipated)	Jun 2027
NCT07273006	Percutaneous Electrical Nerve Stimulation As Alternative To Nerve Blocks In Anesthesia, Pain Medicine And Rehabilitation Of Nonspecific Chronic Pain	82	Aug 2029
NCT04243915	Effectiveness of Percutaneous Neuromuscular Electrical Stimulation on Lumbar Multifidus in Combination With a Protocol of Motor Control Exercises in Patients With Chronic Low Back Pain	64	Dec 2024 (unknown status)
Completed			
NCT01996254 ^a	A Randomized, Double-Blinded, Placebo-Controlled, Multicenter Pilot Study of the SPRINT Peripheral Nerve Stimulation (PNS) System for the Treatment of Post-Amputation Pain	28 (actual)	Jan 2019
NCT05644639 ^a	StimRouter Genicular NeuromoduLation for Chronic KnEe OsteoArthritic Pain	13 (actual)	Jun 2024
NCT03913689 ^a	A Prospective, Open-label, Long-term, Multi-center, Registry to Assess the Safety and Efficacy of the Bioness StimRouter Neuromodulation System in Subjects With Chronic Pain of Peripheral Nerve Origin	62 (actual)	Jun 2024
Unpublished			
NCT04442321	Effectiveness of Ultrasound-Guided Percutaneous Electrical Stimulation on Radial Nerve With Exercises in Patients With Lateral Epicondylalgia	60	Dec 2024 (actual)

NCT: national clinical trial; PNS: peripheral nerve stimulation.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. New policy.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes and CPT coding update
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Title changed from "Peripheral Subcutaneous Field Stimulation" to "Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain". Extensive policy revisions. Added a <i>Note</i> after the INV statement listing the examples of implantable nerve stimulation devices.
12/12/2023	Coding Update

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03/27/2024	Coding Update
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2024	Coding update
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2026	Medical Policy Committee review
08/12/2026	Medical Policy Implementation Committee review
08/20/2026	Medical Quality Management Committee approval. Added examples of <i>Neuspera Neurostimulation System</i> , <i>Neuspera Nuity System</i> to the <i>Note</i> after the investigational statement. Coverage eligibility unchanged.
09/03/2026	Medical Policy Committee review
09/09/2026	Medical Policy Implementation Committee review
09/17/2026	Medical Quality Management Committee approval. Title changed from “Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain” to “Implantable Peripheral Nerve Stimulation Devices”. Revised the investigational statement for implantable peripheral nerve stimulation for the treatment of acute and chronic pain to include non-limiting indications. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64555, 64575, 64590, 64596, 64597, 64598, 64999
HCPCS	A4438, C1767, C1778, C1787, C1816, C1883, C1897, C9807, L8678, L8979, L8680, L8681, L8683
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from

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carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.