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MEDICAL POLICY – 7.01.574

Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain and Other Conditions

BCBSA Ref. Policy 1.01.31, 7.01.29, 7.01.106

Effective Date:	Sept. 1, 2024
Last Revised:	Aug. 12, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

1.01.24	Interferential Current Simulation
1.01.507	Electrical Stimulation Devices
7.01.588	Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
7.01.125	Occipital Nerve Stimulation
7.01.139	Peripheral Subcutaneous Field Stimulation
7.01.546	Spinal Cord and Dorsal Root Ganglion Stimulation

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Peripheral nerves are the nerves that connect the brain and the spinal cord to the body. Peripheral nerve stimulation involves the implantation of a small device that sends low levels of electricity to part(s) of the nerve. This electrical current interferes with the transmission of nerve signals and is thought to reduce pain, or improve muscle movement. Stimulating part(s) of a peripheral nerve to try to treat pain and other conditions, such as urinary incontinence, is investigational. That means this technique needs more study to see if it is safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Implantable peripheral nerve stimulation	**A trial or permanent placement of an implantable peripheral nerve stimulator for the management of chronic pain or other conditions is investigational for all indications.**

Coding

Code	Description
CPT	
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous (new code effective 1/1/2024)
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial (new code effective 1/1/2024)
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous (new code effective 1/1/2024)
0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial (new code effective 1/1/2024)
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

Code	Description
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array (new code effective 1/1/2024)
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure) (new code effective 1/1/2024)
64999	Unlisted procedure, nervous system (if used for Reactiv8)
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

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."

Evidence Review

Description

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.

Background

Peripheral 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.[1], Chronic pain of peripheral origin may be caused by damage to peripheral nerves impacting the upper and lower extremities.

Peripheral Nerve Stimulation

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 guidance and can be placed for temporary or permanent use in an outpatient procedure.

PNS is similar to spinal cord stimulation in that it is typically a two-step process. Initially, a temporary electrode is temporarily implanted for a trial period, usually less than 5 days. The electrode is connected to an external device, and if it successfully reduces the pain by at least 50%, then either a multi-electrode lead is permanently implanted and connected to a pulse generator placed in the body or the electrode responds to a hand-held, wireless external pulse transmitter that individuals control according to their pain management needs via a patient programmer.

Implantable PNS differs from other electrical stimulation therapies in that the origin of pain is from a peripheral nerve and the electrical impulses are delivered directly to the nerve versus the surrounding tissues or spine.

Other electrical stimulation therapies:

- Spinal cord stimulation delivers electrical impulses to the spine.
- Transcutaneous electrical nerve stimulation (TENS) delivers electrical impulses to the surface of the skin at the site of pain.
- Percutaneous electrical nerve stimulation (PENS) delivers electrical impulses via needle electrodes inserted into the skin around or immediately adjacent to the nerves serving the painful area. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted.
- Percutaneous neuromodulation therapy (PNT) delivers electrical impulses through very thin filament electrode arrays inserted directly into the deep tissues near the area causing the pain. (e.g., Deepwave, Percutaneous Neuromodulation Therapy)
- Peripheral subcutaneous field stimulation (PSFS) delivers electrical impulses via electrodes placed subcutaneously under the skin over the area of maximal pain. In peripheral nerve field stimulation, a field of pain is targeted rather than specific nerves. (e.g., SPRINT)

ReActiv8 Implantable Neurostimulation System

ReActiv8 Implantable Neurostimulation System (Mainstay Medical, Ltd) is an implantable electrical neurostimulation system that stimulates the nerves that activate the lumbar multifidus muscles which are key in stabilizing the lower back and thereby, aid in the treatment of chronic low back pain. Prior to implantation, multifidus muscle dysfunction (muscle atrophy and weakness) should be demonstrated during a physical exam using the prone instability test or as seen on magnetic resonance imaging (MRI). The components of the system include: the

implanted pulse generator including two leads and four electrodes and a patient activator (a handheld battery-operated unit that communicates with the pulse generator). It is to be used for 30 minutes twice daily while in a prone or lateral position.

eCoin Implantable Peripheral Neurostimulator

The eCoin Peripheral Neurostimulator System is a coin-sized leadless battery-powered implant that delivers electrical stimulation to the tibial nerve (0.5-15 mA, 20 Hz frequency). The recommended treatment duration is 30 minutes every 3 days for the first 18 weeks (42 sessions) and every 4 days thereafter and is programmed by the clinician. A patient controller can be leveraged to inhibit an automatic session in the event of undesired or painful stimulation. The battery life is estimated at up to 3 years (range, 1-8 years).

Summary of Evidence

For individuals who have peripheral, neuropathic, chronic pain who receive peripheral nerve stimulation (PNS), the evidence includes one randomized controlled trial (RCT). Relevant outcomes are symptoms, medication use, and quality of life The RCT reported a statistically significant difference between the treatment group and control group at 90 days in mean reduction in average pain from baseline (27.2% vs. 2.3%; $p<.0001$) and reported 38% responders, defined as having at least a 30% decrease in the numerical rating scale (NRS) with no upward titration in pain medications, in the treatment group. The RCT had a sample size of 94 with broad descriptions of pain diagnoses, including diagnoses beyond the labeled indications, and a lack of sample population diversity that is not generalizable to the US. There was 51% missing follow-up data at 12 months. 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.

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.

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and who have failed behavioral and pharmacologic therapy or who have responded to an initial course of percutaneous tibial nerve stimulation (PTNS) and then receive subcutaneous implantable tibial nerve stimulation, the evidence includes single-arm studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The pivotal open-label, single-arm study leading to US Food and Drug Administration (FDA)-approval of the subcutaneous implantable, wireless eCoin tibial nerve stimulation system demonstrated a 68% response rate at 48 weeks of follow-up which surpassed a performance goal of 40%. However, the certainty of the evidence is limited by the lack of comparator group and a lower response rate observed during the COVID-19 pandemic. Additionally, the FDA noted that the performance goal was identified after patients had already been implanted. An ongoing post-approval study may elucidate the certainty of benefit, including safety of reimplantation given battery lifespan concerns. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trial that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02873312[a]	Overactive Bladder Treatment Using StimRouter Neuromodulation System: A Prospective Randomized Trial	180	July 2021
NCT05644639[a]	StimRouter Genicular NeuromoduLation for Chronic KnEe OsteoArthritic Pain	30	Jan 2024
NCT03877653	Double-blinded Randomized Control Trial of Knee Pain Utilizing Sub-Threshold Peripheral Nerve Stimulation	100	June 2026

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05287373[a]	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain	150	Sept 2024
NCT04803214	ReActiv8 Stimulation Therapy vs Optimal Medical Management: A Randomized Evaluation (RESTORE)	228	July 2025
NCT05870124[a]	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain (COMFORT 2)	100	Apr 2025
NCT05882318[a]	Evaluating Effectiveness of Sensory and Subsensory Stimulation Amplitudes With eCoin Tibial Nerve Stimulation in Urgency Urinary InContinence Episodes and Quality of Life (ESSENCE)	50	Jul 2024 (recruiting)
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	173	April 2028

NCT: national clinical trial

[a] Denotes industry-sponsored trial

Practice Guidelines and Position Statements

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

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.

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.[9] 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	Grade or LOE[a]	DOR[a]
Upper Extremities		
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
Lower Extremities		
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.

Medicare National Coverage

Medicare has a national coverage determination for Electrical Nerve Stimulators (160.7) for implanted peripheral nerve stimulators since 1995.[11,]

Effective 8/27/2018, Noridian Healthcare Solutions, LLC. Jurisdiction J-F. Local Coverage Determination (L37360) PNS. Revised 1/1/2019[12]

> Peripheral nerve stimulation (PNS) may be covered for relief of chronic intractable pain for individuals with conditions known to be responsive to this form of therapy, and only after attempts to cure the underlying conditions and appropriate attempts at medication management, physical therapy, psychological therapy, and other less invasive interdenominational treatments. As with spinal nerve stimulators, severe neuropathic pain is typically well suited for successful responses to PNS. There may be rare, selected situations where both spinal cord stimulators and peripheral neurostimulators are used together.

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.[52]

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."

Regulatory Status

A number of PNS devices have been cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process. These are listed in **Table 3.**

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 3. 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	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

Device Name	Manufacturer	Cleared	510 (k)	Indications
Trial/Extension Lead Kits, Patient Kits and miscellaneous replacement kits				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 (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

Device Name	Manufacturer	Cleared	510 (k)	Indications
				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.

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.[2]

Product Code: QLK

In March 2022, the eCoin Peripheral Neurostimulator System (Valencia Technologies Corporation) became the first subcutaneous tibial nerve stimulation implant approved by the FDA through the premarket authorization (PMA) process for individuals with urgency urinary incontinence (P200036) who have had an inadequate response to conservative treatment or who have undergone a successful trial of percutaneous tibial nerve stimulation.

FDA Product Code: QPT.

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History

Date	Comments
08/01/19	New policy, approved July 9, 2019, effective November 1, 2019. Add to Surgery section. Implantable peripheral nerve stimulation for the treatment of chronic pain of peripheral nerve origin is investigational.
10/01/20	Annual Review, approved September 1, 2020. Policy reviewed. Reference added. Policy statement unchanged.
04/01/21	Annual Review, approved March 2, 2021. Policy reviewed. References added. Policy statement unchanged.
07/01/21	Coding update, Added HCPC codes C1767 and C1778.
01/01/22	Coding update, updated description for CPT cod 64575.
03/01/22	Annual Review, approved February 21, 2022. Policy reviewed. References added. Policy statement unchanged.
06/01/22	Interim Review, approved May 10, 2022. Policy title changed to Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain from Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain of Peripheral Nerve Origin. Policy reviewed. References added. Policy statement unchanged. ReActiv8 implantable neurostimulation system content added and its use considered investigational. Added HCPCS code C1787.
04/01/23	Annual Review, approved March 20, 2023. Policy reviewed. References added. Policy statement unchanged.
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.
11/01/23	Interim Review, approved October 10, 2023.Policy title changed from “Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain” to “Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain and Other Conditions.” Policy statement modified to include treatment of chronic pain and "other conditions" to cover new background information on eCoin implantable tibial nerve stimulation. References added. Added CPT 64999 for Reactiv8.
01/01/24	Coding update. Added new CPT codes 0816T-0819T, 64596 and 64597.

Date	Comments
09/01/24	Annual Review, approved August 12, 2024. Policy reviewed. References added and deleted. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.