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Implantable Peripheral Nerve Stimulation for Chronic Pain Conditions

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Related Policies (if applicable)
SUR712.009 Spinal Cord Stimulation (SCS) and Dorsal Root Ganglion (DRG) Stimulation

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Peripheral nerve stimulation as a treatment for chronic pain **is considered experimental, investigational, and/or unproven.**

Policy Guidelines

Spinal cord and dorsal root ganglion stimulation are covered in policy SUR712.009 and are not reviewed herein.

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

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.

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

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.

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. Please refer to <https://accessdata.fda.gov> for additional FDA approved PNS devices.

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 1. FDA-Cleared Peripheral Nerve Stimulation Devices (FDA Product Code: 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.
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 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.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Peripheral Nerve Stimulation (PNS) for Chronic Neuropathic Pain

Clinical Context and Therapy Purposep

The purpose of PNS in individuals who have peripheral neuropathic chronic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population(s) of interest are individuals with peripheral neuropathic chronic pain which may be caused by damage to peripheral nerves impacting the upper and lower extremities that is persistent for longer than 3 months. This population does not include individuals with chronic pain such as craniofacial, migraine, low back and trunk, amputation, or post-traumatic pain.

Interventions

The therapy being considered is PNS. 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.

Comparators

The following therapies are currently being used to make decisions about PNS: pharmacologic and nonpharmacologic treatments.

Outcomes

The general outcomes of interest are symptoms, medication use, and quality of life.

As a chronic condition, follow-up of at least 6 weeks to 12 months would be desirable to assess outcomes in chronic neuropathic pain.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommends that chronic pain trials should consider assessing outcomes representing 6 core domains: pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition. (2) Table 2 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT. (3)

Table 2. Health Outcome Measures Relevant to Individuals with Chronic Pain

Outcome	Measure (Units)	Description	Thresholds for Improvement/Decline or Clinically Meaningful Difference (If Known)
Pain intensity	0 to 10 numeric rating scale	Patient reported rating of pain intensity	Minimally important (10 to 20% decrease) Moderately important (≥30% decrease) Substantial (≥50% decrease)
Physical functioning	Multidimensional Pain Inventory Interference Scale	A 60-item self-report inventory of patients' cognitive, behavioral, and affective responses to their condition. Decreasing score indicates improvement	Clinically important (≥0.6 point decrease)
	Brief Pain Inventory Interference Scale	A 7-item self-report assessment of pain interference with physical and emotional functioning and sleep. Decreasing score indicates improvement	Minimally important (1 point decrease)
Emotional functioning	Beck Depression Inventory (score)	Assessment of depression severity ranging from 0 to 63. Decreasing score indicates improvement	Clinically important (≥5 point decrease)
Profile of Mood States	Total Mood Disturbance (score).	A 65-item checklist of mood disturbances with 6 subscale scores. Decreasing score indicates improvement.	Clinically important (≥10 to 15 point decrease).
	Specific Subscales (score).		Clinically important (≥2 to 12 point change).

Global Rating of Improvement	Patient Global Impression of Change (rating)	A single-item rating by participants of their response to treatment in a clinical trial using a 7-point rating scale, ranging from "very much improved" to "very much worse"	Minimally important: "minimally improved" Moderately important: "much improved" Substantial: "very much improved"

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Char et al. (2022) conducted a systematic review evaluating 14 prospective studies (3 RCTs) on the efficacy of implantable PNS for peripheral neuropathic pain. (4) A majority of the studies included were case series or open-label studies. Meta-analyses were not performed. The review found moderate-quality evidence for phantom limb pain and low-quality evidence for other conditions such as complex regional pain syndrome, shoulder pain, post-surgical pain, and mononeuropathies. Limitations included high heterogeneity across studies, small sample sizes, short follow-up durations, lack of control groups in many studies, and potential attrition bias. Additionally, several studies only analyzed patients who responded positively to PNS, which may overestimate efficacy. The authors noted the need for more robust, well-powered RCTs to confirm study findings and better understand long-term outcomes.

Randomized Controlled Trials

StimRouter Neuromodulation System

Deer et al. (2016) conducted an RCT to assess the safety and efficacy of PNS using the StimRouter Neuromodulation System to treat individuals with chronic pain of peripheral nerve origin. (5) Participants (N=94) were randomized 1:1 into the treatment (n=45) or control (n=49) group. The treatment group received PNS and a stable dose of pain medications, and the control group received no PNS and a stable dose of pain medications for 90 days. After 90 days, crossover from the control group to the treatment group was offered. Study visits were planned at 30, 60, and 90 days after randomization, with follow-up at 6 and 12 months. The primary outcomes were pain relief and safety. Average pain at rest was measured by a numerical rating scale (NRS) over 3 months and safety was assessed by adverse events reported

during the 1-year study period. A responder was defined as having at least a 30% decrease in the NRS with no upward titration in pain medications. Secondary outcomes included changes in medication, quality of life, patient global impression of change scale (PGIC), and change in worst pain using the NRS. At 90 days, there was a statistically significant difference between the treatment group and control group in the mean reduction in average pain from baseline (27.2% vs. 2.3%; p<.0001). There were statistically significantly more responders in the treatment group compared to the control group (38% vs. 10%; p=.0048). At 90 days, the treatment group compared to the control group had a significantly better improvement in quality of life (change from baseline [mean ± standard deviation {SD]: 1.4 ± 5.9 vs. -0.2 ± 3.4; p=.037) and PGIC (mean ± SD: 4.8 ± 1.5 vs. 2.5 ± 1.9; p<.0001). There were no device related serious adverse events through follow-up (mean duration: 320 days). Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

SPRINT Peripheral Nerve Stimulation System

Gilmore et al. (2019) conducted a multicenter, randomized, double-blinded, placebo-controlled trial evaluating the efficacy of a 60-day PNS treatment using the SPRINT PNS System for chronic neuropathic postamputation pain in lower extremity amputees (N=28). (6) Participants were randomized to active PNS (n=12) or sham stimulation (n=14). After the initial 4 weeks, the sham stimulation group was given the option to cross over to active PNS. There was a statistically significantly higher responder rate (≥50% pain reduction) in the active PNS group compared to the sham stimulation group at 4 weeks (58% vs 14%; p=.037) and at 8 weeks (67% vs. 14%; p=.014). There were 22 study-related events in 46% (13/28) of participants. The authors noted several limitations including the small sample size, partial crossover design limiting long-term placebo comparison, variability in opioid use, and optional lead replacement at crossover, which may have affected outcomes. Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

Gilmore et al. (2019) reported the 12-month results of their study to evaluate the long-term efficacy of a 60-day PNS treatment for chronic post-amputation pain. (7) The active treatment group (Group 1) received 8 weeks of active PNS, while the sham group (Group 2) received 4 weeks of sham stimulation followed by 4 weeks of active PNS in a partial crossover design. After the 8-week treatment period, all leads were removed and both groups were followed monthly for up to 12 months post-initial implantation. At 12 months, the response rate of Group 1 was statistically significantly higher than that of Group 2 at the end of the initial 4-week placebo period (67% vs. 0%; p=.001). Additionally, 56% of the active group reported ≥50% reductions in pain interference, with significant improvements in depression scores (BDI-II) and PGIC. No serious adverse events were reported. Limitations included the small sample size, optional and inconsistently applied lead replacement in the sham group after crossover, lack of time-matched placebo comparisons, and potential bias from missing data imputation. Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

Ilfeld et al. (2021) conducted a multicenter, randomized, double-masked, sham-controlled pilot study evaluating the efficacy of PNS using the SPRINT PNS System for postoperative pain

management following ambulatory orthopedic surgeries (N=65). (8) Patients were randomized to receive either active PNS (n=31) or sham stimulation (n=34) for 14 days postoperatively. The active PNS group show statistically significantly lower opioid consumption with a median of 5 mg (interquartile range [IQR]: 0, 30) vs. 48 mg (IQR: 25, 90) in the sham group (ratio of geometric means: 0.20; 97.5% confidence interval [CI]: 0.07 to 0.57; p<.001) and lower average pain scores 1.1 ± 1.1 vs. 3.1 ± 1.7 (mean difference: -1.8; 97.5% CI: -2.6 to -0.9; p<.001). A limitation of this study was the treatment duration was for 14 days postoperatively. A responder outcome was not provided, so no further summary of results are included below. Study characteristics are summarized in Table 3. Study limitations are summarized in Tables 5 and 6.

Goree et al. (2024) conducted a multicenter, randomized, double-blind, placebo-controlled trial, evaluating the efficacy of a 60-day PNS treatment using the SPRINT PNS System for persistent postoperative pain following total knee arthroplasty (TKA) (N=52). (9) Patients were randomized to receive active PNS (n=20) or sham stimulation (n=21). Results showed a significantly greater proportion of those receiving PNS achieved ≥50% pain relief during weeks 5 to 8 compared to placebo (60% vs. 24%; p=.028), with corresponding improvements in walking ability (+47% vs. -9%; p=.048) and function (The Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] total score improvement: 62% vs. 35%; p=.006). Quality of life also improved more in the PNS group, with 90% reporting benefit (PGIC ≥1) versus 55% in the placebo group (p=.031). The study reported no serious or unanticipated adverse events. Limitations included the small sample size, a high loss to follow-up, and early study termination due to COVID-19-related enrollment challenges. Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

Nalu Neurostimulation System

Hatheway et al. (2024) conducted a multicenter RCT evaluating the safety and efficacy of PNS using the Nalu Neurostimulation System for treating chronic peripheral neuropathic pain (COMFORT Study) (N=131). (10) Patients were randomized to receive either PNS with conventional medical management (CMM) (n=58) or CMM alone (n=31), with 46 and 31 subjects respectively included in the modified intention-to-treat population. At 3 months, the responder rate (≥50% pain reduction) in the PNS with CMM arm compared to the CMM alone arm was statistically significantly higher (84% vs. 3%; p<.001) and as well as the pain reduction (67% vs. 6%; p<.001). These results were sustained at 6 months, with an 88% responder rate and 70% pain reduction in the PNS with CMM arm. There were no serious adverse events. Limitations included the lack of blinding, the short 3-month duration of the control arm, a disproportionate number of female participants (70%), and high attrition after randomization. Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

Hatheway et al. (2024) reported the 12-month results of the COMFORT Study. (11) Patients from the CMM alone arm were given the option to cross over to the PNS with CMM arm after the initial 3 months. At 12 months, 87% of participants (53/61) were responders (≥50% pain reduction) with a mean pain score reduction from 7.5 ± 1.2 to 2.3 ± 1.7 (p<.001). High

responders (≥80% pain reduction) comprised 31% of the cohort. There were no serious adverse events. Limitations include the lack of blinding, a short control arm duration (3 months), absence of standardized neuropathic pain questionnaires, variability in conventional medical management, and a high attrition after randomization. Study characteristics and results are summarized in Tables 3 and 4a/4b. Study limitations are summarized in Tables 5 and 6.

Table 3. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Treatment	**Control**
Deer et al. (2016) (5)	U.S.	13	NR	Individuals with chronic pain of peripheral nerve origin.	PNS and a stable dose of pain medications for 90 days with up to 12 month follow-up (n=45).	No PNS and a stable dose of pain medications for 90 days, then option to crossover to treatment with up to 12 month follow-up (n=49).
Gilmore et al. (2019) (6) Gilmore et al. (2019) (7)	U.S.	6	2015-2018	Individuals who underwent traumatic lower extremity amputation and were experiencing chronic neuropathic pain.	Active PNS for 4 weeks, with an optional extension to 8 weeks (n=12).	Sham stimulation for 4 weeks, with cross-over to active PNS for an additional 4 weeks (n=14).
Ilfeld et al. (2021) (8)	U.S.	7	2019-2020	Adult patients (≥18 years) scheduled for ambulatory orthopedic surgeries.	Active PNS for 14 days post-operatively (n=31).	Sham stimulation for 14 days postoperatively (n=34).
Goree et al. (2024) (9)	U.S.	11	2020-2023	Adults (≥21 years) who had undergone primary unilateral TKA and continued to experience moderate-to-severe persistent postoperative pain (≥5/10 on the Brief Pain	Active PNS for 60 days (n=20).	Sham stimulation for 60 days (n=21).

				Inventory) for at least six months post-surgery.		
Hatheway et al. (2024) (10) Hatheway et al. (2024) (11)	U.S.	20	2022 (on-going)	Adults aged 18 to 80 with chronic (≥6 months), intractable peripheral neuropathic pain in the low back, shoulder, knee, or foot/ankle, who had not responded adequately to conventional medical management (CMM). Subjects were required to have a pain score ≥6 and stable pain medication use for at least 30 days prior to enrollment.	PNS+CMM arm received a trial implant of the Nalu Neurostimula-tion System. Those achieving ≥50% pain relief during the trial proceeded to permanent implantation and continued with CMM (n=58).	CMM-only arm continued with their existing medical management regimen. At 3 months, they had the option to cross over to the treatment arm if they met specific criteria (e.g., <50% pain reduction, investigator approval) (n=31).

CMM: conventional medical management; NR: not reported; PNS: peripheral nerve stimulation; RCT: randomized controlled trial; TKA: total knee arthroplasty; U.S. United States.

Table 4a. Summary of Key RCT Results

Study	**Mean Pain Reduction from Baseline (%)**	**Responders (%)**	**Pain Medication Increased, n (%)**
StimRouter Neuromodulation System			
	3 Months	3 Months	3 Months
Deer et al. (2016) (5)	N=94	N=94	N=94
Treatment (n=45)	27.2	38	1 (2.2%)
Control (n=49)	2.3	10	2 (4.1%)
p-value	<.0001	.0048	NR
SPRINT Peripheral Nerve Stimulation System			

Gilmore et al. (2019) (6)			4 Weeks	8 Weeks (control crossed over to treatment)	
Treatment (n=12)			58	67	
Control (n=14)			14	14	
p-value			0.37	0.14	
Gilmore et al. (2019) (7)			12 Months		
Treatment (n=9)			67		
Control (n=14)			0 (at end of 4 weeks before cross-over)		
p-value			.001		
Goree et al. (2024) (9)	5 to 8 Weeks		5 to 8 Weeks		
Treatment (n=20)	54		60		
Control (n=21)	26		24		
p-value	.0021		.028		
Nalu Neurostimulation System					
Hatheway et al. (2024) (10)	3 Months	6 Months	3 Months	6 Months	
Treatment (n=46)	67	70	84	88	
Control (n=31)	6	NA	3	NA	
p-value	<.001	NA	<.001	NA	
Hatheway et al. (2024) (11)	12 Months		12 Months		
Treatment (n=61)	69		87		
p-value	NR		NR		

NA: not applicable; NR: not reported; NS: not significant; PGIC: patient global impression of change; RCT: randomized controlled trial; SD: standard deviation.

Table 4b. Summary of Key RCT Results

Study	**Quality of Life, mean ± SD**			**PGIC, mean ± SD**
StimRouter Neuromodulation System				
	Baseline	3 Months	Change	3 Months
Deer et al. (2016) (5)	N=94	N=94	N=94	N=94
Treatment (n=45)	35.5 ± 4.9	36.9 ± 4.5	1.4 ± 5.9	4.8 ± 1.5
Control (n=49)	36.0 ± 4.3	35.8 ± 4.3	-0.2 ± 3.4	2.5 ± 1.9
p-value	.389	250	.037	<.0001
SPRINT Peripheral Nerve Stimulation System				

Gilmore et al. (2019) (6)				4 Weeks	8 Weeks (control crossed over to treatment)
Treatment (n=12)				1.4 ± 1.1	2.2 ± 0.9
Control (n=14)				0.6 ± 1.3	1.3 ± 1.0
p-value				NS	<.01
Gilmore et al. (2019) (7)				3 Months	12 Months
Treatment (n=9)				1.9 ± 0.9	1.8 ± 1.3
Control (n=14)				1.0 ± 0.8	1.2 ± 1.5
p-value				<.05	NS
Goree et al. (2024) (9)					
Treatment (n=20)					
Control (n=21)					
p-value					
Nalu Neurostimulation System					
Hatheway et al. (2024) (10)					
Treatment (n=46)					
Control (n=31)					
p-value					
Hatheway et al. (2024) (11)					
Treatment (n=61)					
p-value					

NS: not significant; PGIC: patient global impression of change; RCT: randomized controlled trial; SD: standard deviation.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Deer et al. (2016) (5)	2. Types of pain medication not reported; Broad descriptions of pain sites; 4. Population is not representative of U.S. diversity.			6. Clinically significant difference not supported.	1. Not sufficient duration for durability.

Gilmore et al. (2019) (6) Gilmore et al. (2019) (7)			5. Cross-over design after initial 4 weeks.		
Ilfeld et al. (2021) (8)					1. Not sufficient treatment duration for benefit (14 days).
Goree et al. (2024) (9)					1. Not sufficient treatment duration for durability. 3. Terminated early due to COVID-19-related enrollment challenges.
Hatheway et al. (2024) (10) Hatheway et al. (2024) (11)	5. Disproportio-nate number of female participants (70%).	5. Adjunct to conventional medical management, which was varied among participants and not clearly defined.	5. Cross-over design after initial 3 months.		

U.S.: United States.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Complete-ness[d]	Power[e]	Statistical[f]
Deer et al. (2016) (5)			1. Not registered on clinicaltrials.gov	1. High loss to follow-up.		
Gilmore et al. (2019) (6) Gilmore et al. (2019) (7)				1. High loss to follow-up.		
Ilfeld et al. (2021) (8)						
Goree et al. (2024) (9)				1. High loss to follow-up.		
Hatheway et al. (2024) (10) Hatheway et al. (2024) (11)		1. Participants and study staff not blinded.		1. High loss to follow-up.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Nonrandomized studies have been published (12-15) but do not provide additional information on safety, efficacy, or subgroups beyond what is available in the RCT and will not be reviewed in detail here.

Section Summary: Peripheral Nerve Stimulation for Chronic Neuropathic Pain

The evidence includes several RCTs. Relevant outcomes are symptoms, medication use, and quality of life. Statistically significant differences in responder rates were reported in the RCTs ranging from 38% to 88% in the treatment groups and 0% to 24% in the control groups. Overall limitations of the current evidence includes small sample sizes, heterogeneous patient populations, high attrition rates, differences in responder definitions, and lack of long-term follow-up data. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data are necessary to assess the efficacy and durability of PNS.

Summary of Evidence

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

Practice Guidelines and Position Statements

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. (16) Relevant recommendations for best practices pertinent to this policy are listed below in Table 7.

Table 7. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished trials that might influence this policy are listed in Table 8.

Table 8. Summary of Key Trials

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	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 2025
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

NCT: national clinical trial; No.: number.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	64555, 64575, 64580, 64585, 64590, 64595, 64596, 64597, 64598, 64999, 95970, 95971, 95972
HCPCS Codes	A4438, A4595, C1767, C1778, C1787, C1816, C1820, C1822, C1883, C1897, C9807, L8678, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	New medical document originating from 205.036 without change to coverage position. Peripheral nerve stimulation as a treatment for chronic pain is considered experimental, investigational, and/or unproven.