PHP_1.01.31	Implantable Peripheral Nerve Stimulation for Chronic Pain Conditions		
Original Policy Date:	December 1, 2025	**Effective Date:**	December 1, 2025
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 16

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

I. Peripheral nerve stimulation as a treatment for chronic pain is considered **investigational**.

Policy Guidelines

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."

Coding

See the Codes table for details.

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.

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 includes small sample sizes, heterogeneous patient populations, high attrition rates, and lack of long-term follow-up data. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data are necessary to assess the efficacy and durability of PNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

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.

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

Device Name	Manufacturer	Cleared	510(k)	Indications
				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 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 (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.
Stimulator, Stimulator Kit, External Transmitter, External Transmitter Kit	Micron Medical Corporation	Aug 2020	K200848	Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Moventis PNS is not intended to treat pain in the craniofacial region.
Neuspera Neurostimulation System (NNS)	Neuspera Medical, Inc.	Aug 2021	K202781	The Neuspera Neurostimulation System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.
Neuspera Nuity System	Neuspera Medical, Inc.	April 2023	K221303	The Neuspera Nuity™ System (NNS) is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

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.

Literature Review

Evidence reviews 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 for Chronic Neuropathic Pain

Clinical Context and Therapy Purpose

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 review.

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 or migraine 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.

Review of Evidence

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

StimeRouter 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 ± 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 4. 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 4. 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 4. 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 (IQR: 0, 30) vs. 48 mg (IQR: 25, 90) in the sham group (ratio of geometric means: 0.20; 97.5% 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 4. 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 4. 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 4. 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]	US	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]	US	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]	US	7	2019-2020	Adult patients (≥18 years) scheduled for ambulatory orthopedic surgeries.	Active PNS for 14 days postoperatively (n=31).	Sham stimulation for 14 days postoperatively (n=34).
Goree et al (2024)[9]	US	11	2020-2023	Adults (≥21 years) who had undergone primary unilateral total knee arthroplasty (TKA) and continued to experience moderate-to-severe persistent postoperative pain (≥5/10 on the Brief Pain Inventory) for at least six months post-surgery.	Active PNS for 60 days (n=20).	Sham stimulation for 60 days (n=21).
Hatheway et al (2024)[10] Hatheway et al (2024)[11]	US	20	2022 (ongoing)	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	PNS+CMM arm received a trial implant of the Nalu Neurostimulation System. Those achieving ≥50% pain relief during the trial proceeded to permanent	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%

Study	Countries	Sites	Dates	Participants	Interventions	
				management (CMM). Subjects were required to have a pain score ≥6 and stable pain medication use for at least 30 days prior to enrollment.	implantation and continued with CMM (n=58).	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.

Table 4. Summary of Key RCT Results

Study	Mean Pain Reduction from Baseline (%)	Responders (%)		Pain Medication Increased, n (%)	Quality of Life, mean ± SD			PGIC, mean ± SD	
StimeRouter Neuromodulation System									
	3 Months	3 Months		3 Months	Baseline	3 Months	Change	3 Months	
Deer et al (2016)[5]	N=94	N=94		N=94	N=94	N=94	N=94	N=94	
Treatment (n=45)	27.2	38		1 (2.2%)	35.5 ± 4.9	36.9 ± 4.5	1.4 ± 5.9	4.8 ± 1.5	
Control (n=49)	2.3	10		2 (4.1%)	36.0 ± 4.3	35.8 ± 4.3	-0.2 ± 3.4	2.5 ± 1.9	
p-value	<.0001	.0048		NR	.389	.250	.037	<.0001	
SPRINT Peripheral Nerve Stimulation System									
Gilmore et al (2019)[6]		4 Weeks	8 Weeks (control crossed over to treatment)					4 Weeks	8 Weeks (control crossed over to treatment)
Treatment (n=12)		58	67					1.4 ± 1.1	2.2 ± 0.9
Control (n=14)		14	14					0.6 ± 1.3	1.3 ± 1.0
p-value		.037	.014					NS	<.01
Gilmore et al (2019)[7]		12 Months						3 Months	12 Months
Treatment (n=9)		67						1.9 ± 0.9	1.8 ± 1.3
Control (n=14)		0 (at end of 4 weeks before cross-over)						1.0 ± 0.8	1.2 ± 1.5
p-value		.001						<.05	NS
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						

Study	Mean Pain Reduction from Baseline (%)		Responders (%)		Pain Medication Increased, n (%)	Quality of Life, mean ± SD	PGIC, mean ± SD
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 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 US 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. Disproportionate 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.		

US: 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 Completeness[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[12,13,14,15], but do not provide additional information on safety, efficacy, or subgroups beyond what is available in the RCTs 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.

Supplemental Information

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 U.S. professional society, an international society with U.S. 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.[16] Relevant recommendations for best practices pertinent to this review 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.

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.[17]

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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
Completed			
NCT01996254[a]	A Randomized, Double-Blinded, Placebo-Controlled, Multicenter Pilot Study of the SPRINT Peripheral Nerve	28 (actual)	Jan 2019

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Stimulation (PNS) System for the Treatment of Post-Amputation Pain		
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.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	64555	Percutaneous 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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

Type	Code	Description
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	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)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
HCPCS	A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
	C1897	Lead, neurostimulator test kit (implantable)
	L8679	Implantable neurostimulator, pulse generator, any type
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

In making a determination that any procedure, treatment, therapy, drug, biological product, facility, equipment, device, or supply is "experimental or investigational" by the Plan, the Plan shall refer to evidence from the national medical community, which may include one or more of the following sources:

1. Evidence from national medical organizations, such as the National Centers of Health Service Research.
2. Peer-reviewed medical and scientific literature.
3. Publications from organizations, such as the American Medical Association (AMA).
4. Professionals, specialists, and experts.
5. Written protocols and consent forms used by the proposed treating facility or other facility administering substantially the same drug, device, or medical treatment.
6. An expert physician panel selected by one of two organizations, the Managed Care Ombudsman Program of the Medical Care Management Corporation or the Department of Managed Health Care.

Feedback

Blue Shield of California Promise Health Plan is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.