1.01.31	Implantable Peripheral Nerve Stimulation for Chronic Pain Conditions		
Original Policy Date:	September 1, 2024	**Effective Date:**	September 1, 2024
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 12

Policy Statement

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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Spinal cord and dorsal root ganglion stimulation are covered in Blue Shield of California Medical Policy: Spinal Cord and Dorsal Root Ganglion Stimulation 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."

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.

Related Policies

- Percutaneous and Subcutaneous Tibial Nerve Stimulation
- Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy
- Peripheral Subcutaneous Field Stimulation
- Spinal Cord and Dorsal Root Ganglion Stimulation
- Transcutaneous Electrical Nerve Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 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 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 (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

Device Name	Manufacturer	Cleared 510(k)	Indications
			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

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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, 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.	Clinically important (≥10 to 15 point decrease)

Outcome	Measure (Units)	Description	Thresholds for Improvement/Decline or Clinically Meaningful Difference (If Known)
	Specific Subscales (score)	Decreasing score indicates improvement.	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

A systematic review has been published.[4,] The only relevant RCT from the systematic review is discussed in the following section and the systematic review will not be discussed further here.

Randomized Controlled Trials

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.

Table 3. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Treatment (n=45)	Control (n=49)
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.	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.

NR: not reported; RCT: randomized controlled trial

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
	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

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,]	1. Population includes post-traumatic and post-surgical pain, which is not included in FDA approved device indications; 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.

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.		

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[6,7,8,], 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 1 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 in mean reduction in average pain from baseline at 90 days (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.

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 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 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.[10]

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			
NCT05644639[a]	StimRouter Genicular NeuromoduLation for Chronic KnEe OsteoArthritic Pain	30	Jan 2024
NCT05287373[a]	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain	150	Sept 2024
NCT05870124[a]	Clinical Study Of a Micro-Implantable Pulse Generator For The Treatment of Peripheral Neuropathic Pain (COMFORT 2)	100	April 2025
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 or cosponsored trial.

References

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

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
09/01/2024	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and

effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are 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 or 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.

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California 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 contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
New Policy **Policy Statement:** N/A	**Implantable Peripheral Nerve Stimulation for Chronic Pain Conditions 1.01.31** **Policy Statement:** I. Peripheral nerve stimulation as a treatment for chronic pain is considered **investigational**.