

## Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation

**Policy MP-061**

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### Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### Description:

Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation therapy in which electrodes are surgically placed next to a selected peripheral nerve considered to be the source of chronic pain. (Peripheral nerves are nerves located outside of the brain and spinal cord). In this type of treatment, the electrode(s) delivers electrical impulses to the affected nerve. This electrical current is thought to then disrupt the normal transmission of pain signals leading to reduced levels of pain. During the trial period, the electrode is connected to an external device, and if the trial is successful, a small generator gets implanted into the patient's body.

PNS has been proposed for the treatment of chronic, refractory pain that is nonresponsive to conservative treatments (e.g., neuropathic hemiplegic shoulder pain, back pain, carpal tunnel syndrome; causalgia, complex regional pain syndrome, failed back syndrome, fibromyalgia, hemiplegic shoulder pain, brachial plexus injuries, post-trauma pain, subacromial impingement syndrome, post-amputation pain, post-herpetic neuralgia, stroke, testicular pain, and trigeminal neuropathy).

Peripheral nerve field stimulation (PNFS), also known as subcutaneous peripheral field stimulation, is a recent technology proposed for the treatment of chronic cervical, thoracic, or lumbar pain. Electrode leads are placed in subcutaneous tissue around the painful area, and electrical current is applied to create stimulation in the area, or "field," of pain. This technique is different from peripheral nerve stimulation (PNS), in which specific peripheral nerves are

targeted. In peripheral nerve field stimulation, a field of pain is targeted rather than specific nerves.

## **Policy Statement and Criteria**

### **1. Commercial Plans/CHIP**

**U of U Health Plans does NOT cover peripheral nerve stimulation and peripheral nerve field stimulation (PNFS) as there is insufficient evidence to support the safety and effectiveness. Therefore, it is considered investigational for all indications.**

### **2. Medicaid Plans**

**Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)**

**CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

**Healthy U covers peripheral nerve stimulation (PNS) when ALL of the following requirements have been met:**

- A. Documented chronic and severe pain for at least 3 months;
- B. Documented failure of less invasive treatment modalities and medications;
- C. Lack of surgical contraindications including infections and medical risks;
- D. Appropriate proper patient education, discussion and disclosure of risks and benefits;
- E. No active substance abuse issues;
- F. Formal psychological screening by a mental health professional; and
- G. Successful stimulation trial with greater than or equal to 50% reduction in pain intensity before permanent implantation.

**Healthy U does NOT cover peripheral nerve field stimulation (PNFS) for any indication as it is considered investigational, due to insufficient evidence to support safety and effectiveness.**

## **Clinical Rationale**

*Peripheral Nerve Stimulation (PNS)*

The published peer-reviewed literature demonstrates insufficient evidence to support the safety and effectiveness of implanted PNS for any indication. Studies primarily have small patient populations in the form of case reports, retrospective reviews and case series (n=7–15) (Ilfeld, et al., 2019; Gilmore, et al., June 2019; Gilmore, et al., 2018; Wilson, et al., 2014; Wilson et al., 2017; Stevanato, et al., 2014; Reverberi, et al., 2014; Stidd, 2012).

In a 2015 case-report, (Nguyen et al) describes the 1st participant treated with a fully implantable, single-lead PNS system for refractory hemiplegic shoulder pain. In this 6-week trial stage, a temporary lead was placed percutaneously near the terminal branches of the axillary nerve to the deltoid. The primary outcome measure was the Brief Pain Inventory-Short Form Question 3, a 0 to 10 pain NRS. The participant experienced 75 % pain reduction and proceeded to the implantation stage, where he received a single-lead, implantable pulse generator. After 3 weeks, the participant became pain-free. However, 7 weeks after implantation, the system was turned off because of an unrelated acute medical illness. Hemiplegic shoulder pain re-emerged with a Brief Pain Inventory-Short Form Question 3 score of 9. After 11 weeks of recovery, PNS was re-initiated and the participant became pain-free through the 9-month follow-up. At 12 months, Brief Pain Inventory-Short Form Question 3 score was 1. In conclusion, this report demonstrated the feasibility of a single-lead, fully implantable PNS system for refractory hemiplegic shoulder pain. In 2016, an industry funded crossover study (Deer, et al.), described 94 patients with pain of peripheral origin that were implanted and then randomized to the treatment of 45 patients with peripheral nerve stimulation and 49 patients into the control group. The primary efficacy endpoint was response rate, defined as a 30 percent decrease in a numerical rating scale, with no upward titration in the patient's medication regimen, three months after randomization to treatment. The investigators reported that patients receiving active stimulation achieved a statistically significantly higher response rate of 38% versus the 10% rate found in the control group ( $p = 0.0048$ ). Improvement in pain was statistically significant between the randomized groups, with the treatment group achieving a mean pain reduction of 27.2% from baseline to month 3 compared to a 2.3% reduction in the control group ( $p < 0.0001$ ). During the partial crossover period, patients again demonstrated statistically significant improvement in pain relief with active stimulation compared to baseline. Further, the treatment group had significantly better improvement than the control group in secondary measures including but not limited to quality of life and satisfaction. Safety, assessed throughout the trial and with follow-up to one year, demonstrated no serious adverse events related to the device. The authors concluded, that all device-related adverse events were minor and self-limiting. Further studies confirming these benefits are needed.

In a 2018 case series, Wilson et al., investigated the feasibility and safety of a single-lead, fully implantable PNS system for the treatment of chronic shoulder pain in stroke survivors. Subjects had moderate-to-severe shoulder pain not responsive to conservative therapies for 6 months. During the trial phase, which included a blinded sham introductory period, a percutaneous single-lead PNS system was implanted to stimulate the axillary nerve of the affected shoulder. After a 3-week successful trial, subjects received an implantable pulse generator with an electrode placed to stimulate the axillary nerve of the affected shoulder. Outcomes included pain, pain interference, pain-free external rotation ROM, quality of life (QOL), and safety; subjects were followed-up for 24 months. A total of 28 subjects underwent trial stimulation and 5 participants received an implantable pulse generator. Subjects who received the implantable generator experienced an improvement in pain severity ( $p = 0.0002$ ). All 5 subjects experienced a 50 % or greater pain reduction at 6 and 12 months, and 4 experienced at least a 50 % reduction at 24 months. There was an improvement in pain interference ( $p < 0.0001$ ). There was an improvement in pain-free external ROM ( $p = 0.003$ ). There were no serious AEs related to the device or to the procedure. In conclusion, this study demonstrated the safety and efficacy of a fully implantable axillary PNS system for chronic hemiplegic shoulder pain. Subjects experienced reduction in pain,

reduction in pain interference, and improved pain-free external rotation ROM. There were no serious adverse events associated with the system or the procedure.

In June of 2019, Gilmore et al. conducted a double-blinded, randomized, placebo-controlled study of 28 lower extremity amputees with post-amputation. The subjects underwent ultrasound-guided implantation of percutaneous PNS leads and were randomized to receive PNS (with SPRINT, SPR Therapeutics), or placebo for 4 weeks. The placebo group then crossed over and all subjects received PNS for four additional weeks. The primary efficacy endpoint evaluated the proportion of subjects reporting  $\geq 50\%$  pain reduction during one to four weeks. A greater proportion of subjects receiving PNS ( $n=7/12$ , 58%,  $p=0.037$ ) demonstrated  $\geq 50\%$  reductions in average post-amputation pain during weeks one through four compared with subjects receiving placebo ( $n=2/14$ , 14%). Two subjects were excluded from efficacy analysis due to eligibility changes. Greater proportions of PNS subjects also reported  $\geq 50\%$  reductions in pain ( $n=8/12$ , 67%,  $p=0.014$ ) and pain interference ( $n=8/10$ , 80%,  $p=0.003$ ) after 8 weeks of therapy compared with subjects receiving placebo (pain:  $n=2/14$ , 14%; pain interference:  $n=2/13$ , 15%). In conclusion, this study demonstrates that percutaneous PNS therapy may provide enduring clinically significant pain relief and improve disability in patients with chronic neuropathic post-amputation pain. However, limitations of the study included a small number of subjects.

Then in November of 2019, Gilmore et al reported on the 12 month outcomes from the cohort study conducted by Gilmore et al, in June 2019 (above). It mentioned that more participants in group one reported  $\geq 50\%$  reductions in average weekly pain at 12 months (67%, 6/9) compared with group two at the end of the placebo period (0%, 0/14,  $p=0.001$ ). In addition, 56% (5/9) of participants in group one reported  $\geq 50\%$  reductions in pain interference at 12 months, compared with 2/13 (15%,  $p=0.074$ ) in group two at crossover. The authors concluded that percutaneous PNS delivered over a 60-day period may provide significant carry-over effects including pain relief, potentially avoiding the need for a permanently implanted system while enabling improved function in patients with chronic pain. With limitations of the study including the small number of subjects at 12 months and the loss of participants to follow-up, further robust studies are needed.

In addition, multiple reviews by Hayes, Inc. have noted there is an insufficient quantity of published, peer-reviewed, human clinical data to evaluate the use of either the StimRouter System or the SPRINT PNS System (SPR Therapeutics) for treatment of chronic pain in a health technology assessment (HTA).

Hayes performed a health tech assessment in 2022 on Percutaneous Peripheral Nerve Stimulation for Treatment of Chronic Pain. They "identified 4 eligible studies (in 5 publications) that evaluated percutaneous PNS for the treatment of chronic pain, including: 2 randomized controlled trials (RCTs) comparing PNS with sham PNS that offered an option to cross over to the PNS group and 2 prospective pretest-posttest studies. The maximum period of follow-up ranged from 6 months to 1 year." The authors concluded that "a small, very low-quality body of evidence suggests that percutaneous PNS may be associated with pain reduction and improvement of quality of life, ADLs, and medication utilization rates and appears to be safe. The most common device-related AEs were mild skin irritation and itching at the external implant site. However, the available evidence is insufficient to draw definitive conclusions regarding efficacy and safety. None of the studies meeting inclusion criteria included patient sub-analysis or regression analyses to inform ideal patient selection criteria. Although the preliminary evidence suggests that PNS may benefit some patients with chronic pain, additional well-designed studies with larger populations and comparisons with treatment alternatives are needed to strengthen the reliability of the evidence base and to provide greater confidence in the observed trends." During the 2023 and 2024 annual reviews of the tech assessment on Percutaneous PNS for the Treatment of Chronic Pain, Hayes found "no relevant newly published studies that may meet the inclusion criteria set

out in the report, which was published in 2022.” Therefore, there was no change in the previous rating of a D2.

### Peripheral Nerve Field Stimulation (PNFS)

Randomized controlled clinical trial data, and meta-analyses are lacking in the published, peer-reviewed scientific literature and there is insufficient evidence to determine safety and effectiveness of this therapy. Published peer-reviewed clinical trial data is primarily limited to case series and prospective and retrospective reviews and studies with small number of subjects (McRoberts, et al., 2013; Petersen, et al., 2014; Verrills, et al., 2011; Mitchell, et al., 2016).

A 2018 prospective study (Ishak et al.), assessed the usefulness, safety, and efficacy of subcutaneous peripheral nerve field stimulation, in 26 consecutive patients with chronic low back pain. Two electrodes were implanted vertically at a depth of 1 cm into the subcutaneous tissue,  $\leq 10$  cm from the region of maximum pain. Trial neurostimulation was performed in all patients for 14 days. A successful outcome was defined as at least 50% pain relief and to monitor the effects of permanent neurostimulation, the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI), and quality of life (EQ-5D-3L) were scored preoperatively and at 6-month and 24-month follow-ups. Thirteen patients responded to trial stimulation and had a permanent neurostimulator implanted. The use of pain medication, including opioid analgesics, was reduced in 92% of patients after 24 months. VAS, ODI, and EQ-5D-3L scores were improved in these patients at the 24-month follow-up. The complication rate was 23% (3/13 patients). In non-responders, the VAS and ODI at 24 months dropped as well but the decrease was less pronounced compared to responders and did not lead to decrease in pain medication. The authors concluded that this study included a small number of participants, therefore, larger prospective, randomized, controlled studies are needed to confirm findings.

Hayes most recent update of their health tech assessment of PNFS for the treatment of low back pain on March 16, 2023, noted additional studies that qualified for the review. The authors found that there remains a very low quality body of evidence that does not allow for conclusions regarding the efficacy and safety of PNFS for treatment of chronic low back pain (CLBP). A limited evidence base suggests that PNFS may provide statistically significant pain relief in patients with refractory CLBP, although pain relief did not achieve clinical significance in all studies. PNFS appears to be generally safe, with relatively few complications or adverse events and may also reduce analgesic use along with improving function and QOL. Yet, uncertainty still exists due to limited evidence of comparative effectiveness relative to other interventions for CLBP and limited follow-up data. Furthermore, additional studies are needed to evaluate the long-term efficacy and safety of PNFS versus comparable therapies, such as spinal cord stimulation, and definitive alternatives, such as surgery.

The American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine published practice guidelines for chronic pain management (2010). Regarding subcutaneous peripheral nerve stimulation, the guidelines indicate that studies with observational findings indicate that subcutaneous peripheral nerve stimulation can provide pain relief for assessment periods ranging from four months to two years (Category B2 evidence). [Category B2 evidence: the literature contains non-comparative observational studies with associative (e.g., relative risk and correlation) or descriptive statistics].

## **Applicable Coding**

### CPT Codes

**64555** Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

- 64575** Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
- 64585** Revision or removal of peripheral neurostimulator electrode array
- 64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 64595** Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
- 64999** Unlisted procedure, nervous system
- 95970** Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
- 95971** ; with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
- 95972** ; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

Not covered-investigational

- 0720T** Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

HCPCS Codes

- C1767** Generator, neurostimulator (implantable), non-rechargeable
- C1778** Lead, neurostimulator (implantable)
- C1787** Patient programmer, neurostimulator
- C1816** Receiver and/or transmitter, neurostimulator (implantable)
- C1820** Generator, neurostimulator (implantable), non-high-frequency with rechargeable battery and charging system
- C1822** Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
- C1883** Adaptor/extension, pacing lead or neurostimulator lead (implantable)
- C1897** Lead, neurostimulator test kit (implantable)

- L8679** Implantable neurostimulator, pulse generator, any type
- L8680** Implantable neurostimulator electrode, each
- L8681** Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
- L9682** Implantable neurostimulator radiofrequency receiver
- L8683** Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8685** Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
- L8686** Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
- L8687** Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688** Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
- L8689** External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
- L8695** External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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