

Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation

Policy MP-061

Origination Date: 07/22/2020

Reviewed/Revised Date: 07/21/2021

Next Review Date: 07/21/2022

Current Effective Date: 07/21/2021

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, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

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 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

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

<http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

3. Medicare Plans

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicare policies and coverage, please visit their search website at:

<http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

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, 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).

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, ≤ 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.

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

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

References:

1. American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. 2010 Apr;112(4):810-33
2. Deer T, Pope J, Benyamin R, et al. Prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. *Neuromodulation*. 2016;19:91-100.
3. Gilmore CA, Ilfeld BM, Rosenow JM, Li S, Desai MJ, Hunter CW, Rauck RL, et al. Percutaneous 60-day peripheral nerve stimulation implant provides sustained relief of chronic pain following amputation: 12-month follow-up of a randomized, double-blind, placebo-controlled trial. *Reg Anesth Pain Med*. 2019 Nov 17.
4. Gilmore CA, Kapural L, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation (PNS) for the Treatment of Chronic Low Back Pain Provides Sustained Relief. *Neuromodulation*. 2018 Oct 3.
5. Gilmore, C., et al. (June 2019). "Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial." *Reg Anesth Pain Med* 44(6): 637-645.
6. Hayes, Inc. Hayes Evidence Analysis Research Brief. "Peripheral Nerve Stimulation for Treatment of Back Pain". May 26, 2021. Accessed: July 11, 2021.
7. Hayes, Inc. Hayes Evidence Analysis Research Brief. "Peripheral Nerve Stimulation with the SPRINT PNS System for Chronic Knee Pain". January 8, 2021. Accessed: July 11, 2021.
8. Hayes, Inc. Hayes Evidence Analysis Research Brief. Peripheral Nerve Field Stimulation for Treatment of Back Pain. Lansdale, PA: Hayes, Inc.; Apr 30, 2019. Archived: May 20, 2020.
9. Hayes, Inc. Hayes Evidence Analysis Research Brief. SPRINT PNS System (SPR Therapeutics) For Chronic Pain. Lansdale, PA: Hayes, Inc.; Jan 21, 2019. Archived: June 14, 2021.

10. Hayes, Inc. Hayes Evidence Analysis Research Brief. StimRouter Neuromodulation System (Bioness Inc.) for Treatment of Chronic Pain Hayes, Inc.; June 19, 2020. Archived: July 19, 2021
11. Hayes, Inc. Health Technology Assessment. "Occipital Nerve Stimulation for Chronic Cluster Headache". September 24, 2020. Accessed: July 11, 2021.
12. Hayes, Inc. Health Technology Assessment. "Peripheral Nerve Field Stimulation for Treatment of Chronic Low Back Pain". April 22, 2021. Accessed: July 11, 2021.
13. Health Technology Assessment. "Occipital Nerve Stimulation for Chronic Migraine Headache". June 30, 2020. Accessed: July 11, 2021.
14. Ilfeld BM, Ball ST, Gabriel RA, Sztain JF, Monahan AM, Abramson WB, et al. A Feasibility Study of Percutaneous Peripheral Nerve Stimulation for the Treatment of Postoperative Pain Following Total Knee Arthroplasty. *Neuromodulation*. 2019 Jul;22(5):653-660.
15. International Neuromodulation Society (INS). Peripheral nerve stimulation. Reviewed July 6, 2019. Subcutaneous Peripheral Field Stimulation. Accessed July 10, 2020. Available at URL address: <http://www.neuromodulation.com/PNS>
16. Ishak B, Campos B, Brunn H, Unterberg AW, Ahmadi R. Feasibility, Safety, and Efficacy of Subcutaneous Peripheral Nerve Field Stimulation for the Treatment of Refractory Low Back Pain: A Two-year Single-center Study. *Neuroscience*. 2018 Sep 1;387:38-47.
17. McRoberts WP, Wolkowitz R, Meyer DJ, Lipov E, Joshi J, Davis B, et al. Peripheral nerve field stimulation for the management of localized chronic intractable back pain: results from a randomized controlled study. *Neuromodulation*. 2013 Nov-Dec;16(6):565-74; discussion 574-5.
18. Mitchell B, Verrills P, Vivian D, DuToit N, Barnard A, Sinclair C. Peripheral Nerve Field Stimulation Therapy for Patients With Thoracic Pain: A Prospective Study. *Neuromodulation*. 2016 Oct;19(7):752-759.
19. Nguyen VQ, Bock WC, Groves CC, et al. Fully implantable peripheral nerve stimulation for the treatment of hemiplegic shoulder pain: A case report. *Am J Phys Med Rehabil*. 2015;94(2):146-53.
20. Petersen EA, Slavin KV. Peripheral nerve/field stimulation for chronic pain. *Neurosurg Clin N Am*. 2014 Oct;25(4):789-97.
21. Reverberi C, Dario A, Barolat G, Zuccon G. Using Peripheral Nerve Stimulation (PNS) to Treat Neuropathic Pain: A Clinical Series. *Neuromodulation*. 2014 Feb 14 [Epub ahead of print].
22. Stevanato G, Devigili G, Eleopra R, Fontana P, Lettieri C, Baracco C, et al. Chronic post-traumatic neuropathic pain of brachial plexus and upper limb: a new technique of peripheral nerve stimulation. *Neurosurg Rev*. 2014 Jul;37(3):473-79; discussion 479-80.
23. Stidd, DA, Wuollet, AL, Bowden, K, Price, T, Patwardhan, A, Barker, S, et al. Peripheral nerve stimulation for trigeminal neuropathic pain. *Pain Physician*. 2012;15(1):27-33.
24. Verrills P, Vivian D, Mitchell B, Barnard A. Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. *Pain Med*. 2011 Sep;12(9):1395-405.
25. Wilson RD, Bennett ME, Nguyen VQC, et al. Fully implantable peripheral nerve stimulation for hemiplegic shoulder pain: A multi-site case series with two-year follow-up. *Neuromodulation*. 2018;21(3):290-295.
26. Wilson RD, Gunzler DD, Bennett ME, Chae J. Peripheral Nerve Stimulation Compared to Usual Care for Pain Relief of Hemiplegic Shoulder Pain: A Randomized Controlled Trial. *Am J Phys Med Rehabil*. 2014 Jan; 93(1): 17–28.
27. Wilson RD, Harris MA, Gunzler DD, Bennett ME, Chae J. Percutaneous peripheral nerve stimulation for chronic pain in subacromial impingement syndrome: a case series. *Neuromodulation*. 2014 Dec;17(8):771-6; discussion 776.
28. Wilson RD, Knutson JS, Bennett ME, Chae J. The Effect of Peripheral Nerve Stimulation on Shoulder Biomechanics: A Randomized Controlled Trial in Comparison to Physical Therapy. *Am J Phys Med Rehabil*. 2017 Mar;96(3):191-198.

Disclaimer:

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from U of U Health Plans.

"University of Utah Health Plans" and its accompanying logo, and its accompanying marks are protected and registered trademarks of the provider of this Service and or University of Utah Health. Also, the content of this Service is proprietary and is protected by copyright. You may access the copyrighted content of this Service only for purposes set forth in these Conditions of Use.

© CPT Only – American Medical Association