

MEDICAL POLICY	Percutaneous Neuromodulation Therapy (PNT) (All Lines of Business Except Medicare)
Effective Date: 3/1/2021	Medical Policy Number: 63
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Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Percutaneous neuromodulation therapy (PNT) or percutaneous nerve stimulation (PENS) is considered **investigational and is not covered** as a treatment for any condition including, but not limited to, back and neck pain.

Link to [Policy Summary](#)

BILLING GUIDELINES

There are no specific codes for percutaneous neuromodulation therapy (PNT) or percutaneous nerve stimulation (PENS).

MEDICAL POLICY	Percutaneous Neuromodulation Therapy (PNT) (All Lines of Business except Medicare)
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CPT/HCPCS CODES

All Lines of Business	
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
64999	Unlisted procedure, nervous system
E1399	Durable medical equipment, miscellaneous

DESCRIPTION

For the purposes of this policy percutaneous neuromodulation therapy (PNT) includes percutaneous nerve stimulation (PENS). These terms are often used interchangeably and both combine features of electro-acupuncture and transcutaneous electrical nerve stimulation (TENS), although PENS can also include the use of implanted electrodes. Although the number of needles used in either PENS versus PNT varies, both involve placement of electrode arrays within close proximity to painful areas to stimulate nerves within the soft tissue. Treatment typically consists of two to three 30-minute sessions per week for two to six weeks.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of percutaneous neuromodulation therapy (PNT) as a treatment for chronic pain conditions, including back and neck pain. Below is a summary of the available evidence identified through December of 2020.

Systematic Reviews

- In 2016, Hayes reviewed evidence regarding the efficacy of percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) for the treatment of low back pain.¹ Hayes addresses the two modalities as interchangeable. Hayes indicated that while there is sufficient published evidence in the abstracts to evaluate the use of PNT to treat low back pain, a full review was needed to confirm the conclusions about the safety and effectiveness of the technology. The following studies were included in the Hayes review:

In 2011, Raphael, et al. conducted a small (n=31) randomized double-blind sham-controlled crossover trial to investigate the efficacy of PENS.² There was a statistically significant difference between the changes in the numerical rating scaled for pain for the active therapies compared with the sham therapies, indicating improvement for the active therapies. There was also a statistically significant difference between the changes in pain pressure threshold for the active therapies compared with the sham therapies with the same indication of improvement for the active therapies. Authors suggested PENS therapy appears to be effective in providing short-

term pain relief in chronic pain conditions, but indicated that studies involving larger sample sizes and longer follow-up are recommended.

In 2008, Weiner and colleagues conducted a randomized controlled trial with 200 patients with chronic low back pain to evaluate the efficacy of percutaneous electrical nerve stimulation (PENS) with and without general conditioning and aerobic exercise (GCAE).³ Participants were randomized into one of 4 groups: 1) PENS, 2) control-PENS (brief electrical stimulation to control for treatment expectancy), 3) PENS+GCAE, or 4) control-PENS+GCAE. All groups studied experienced significantly reduced pain, improved self-reported disability and improved gait velocity. This improvement was sustained at a 6 month reassessment. The GCAE groups experienced significantly fewer fear avoidance beliefs immediately post-intervention and at 6 months than non-GCAE groups but was no more effective than PENS alone in pain reduction or improved physical function.

In 2004, Topuz and colleagues compared the efficacy of conventional and low-frequency transcutaneous electrical nerve stimulation (C-TENS, low-TENS) and PNT in sixty patients. The patients were divided into 4 groups (placebo-TENS, C-TENS, low-TENS and PNT). The outcomes indicated that the placebo -TENS group showed no relief of activity pain or improved general health, vitality and emotional role limitation scores of health quality. Improved relief of activity pain and general health was reported with the C-TENS group. Both the low-TENS and PNT groups demonstrated significant improvement in all parameters. Authors concluded PNT was significantly more effective than TENS in providing relief of activity pain and in improving general health, vitality and emotional role limitation scores of health quality. The limitations of this study included small sample sizes and no long term follow up. Additional studies with larger sample sizes and longer term follow-up are needed to validate these results.

- In 2017 (updated 2019), Hayes conducted a re-review of the evidence regarding percutaneous electrical nerve stimulation for treatment of low back pain.⁴ A total of 4 clinical studies were identified (3 randomized and 1 was a pretest/posttest study design). Hayes indicated, “(o)verall, a very-low-quality body of evidence is inconclusive for PENS as monotherapy (n=2 studies) or PENS in combination with physical therapy (PT) or general conditioning and aerobic exercise (GCAE) (n=2 studies) in patients with CLBP [chronic low back pain]. In general, results suggest a short-term (3 months) benefit in pain and pain-related disability from baseline; however, these differences were typically statistically but not clinically significant.”⁴ Study limitations included differences in PENS techniques used between studies, small sample size, nonrandomized design of one study, lack of control arm comparison group, limited follow-up and high dropout rate. Overall, the Hayes review gave a **D2 rating** which reflects the, “very-low-quality body of inconclusive evidence suggesting that the use of PENS for the treatment of CLBP may result in short-term benefits. However, substantial uncertainty remains due to conflicting results in eligible studies, the lack of assessment of long-term outcomes, small sample sizes, and the uncertainty of minimal clinically important differences for some outcomes.”⁴
- In 2016 (updated 2018), ECRI published a rapid review of evidence which evaluated implantable peripheral nerve stimulation to treat trigeminal neuralgia.⁵ A total of 6 case series were identified, two of which had not been published in peer reviewed journals. Overall, the review

MEDICAL POLICY	Percutaneous Neuromodulation Therapy (PNT) (All Lines of Business except Medicare)
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concluded inconclusive evidence, “in size and quality and may not reflect the actual complication rates. Large randomized trials may provide a better evidence base and ability to judge the effectiveness of PNS.”⁵

- In 2020, Plaza-Manzano and colleagues published a systematic review and meta-analysis on the effectiveness of percutaneous electrical nerve stimulation (PENS) for musculoskeletal pain.⁶ Sixteen randomized studies were included in the analysis, three of which were crossover trials. When comparing PENS alone to sham PENS on short-term pain-intensity, PENS showed a large effect ($p < .001$), although this high heterogeneity ($I^2 = 82\%$). PENS alone also showed a significant effect on short-term pain intensity when compared to other interventions ($p = .008$), also with high heterogeneity ($I^2 = 80\%$) between studies. After a subgroup analysis by intervention type, PENS’ significant improvement on pain intensity disappears when compared to exercise therapy and dry needling, but remains when compared to TENS. When comparing PENS plus other intervention to the same intervention along, PENS shows moderate improvement in short-term pain intensity with high heterogeneity, and subgroup analysis show significant efficacy only with knee osteoarthritis and heel pain. PENS alone showed moderate effect on midterm pain intensity and a no effect on related disability, with high heterogeneity among trials.

The authors found the evidence to be of low quality to do inconsistency between trials and a number of trials with an insufficient number of participants to meet the desired significance and power. Due to inconsistencies in trial designs, interventions, indications, and results collected, and lack of long-term follow up, the authors concluded that more high-quality trials are needed to further determine the clinical effects of PENS for musculoskeletal pain.

Randomized and Nonrandomized Studies

Additional studies were identified which were not included in the Hayes review. These included three observational studies with varying samples sizes (10-76), and 2 small randomized trials with 31 and 23 patients.^{2,7-10} The limited evidence available from these studies indicated PNT may be effective for short term pain reduction. However, study limitations included small sample sizes and the lack of long term follow up (the longest follow up was 6 months). Studies with larger sample sizes and longer follow up are recommended to validate efficacy, safety and clinical utility of this treatment.

CLINICAL PRACTICE GUIDELINES

American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), American Academy of Physical Medicine and Rehabilitation (AAPMR)

In 2011, the AAN, AANEM, and AAPMR published evidence-based guidelines for the treatment of diabetic neuropathy. The guidelines recommend that percutaneous electrical nerve stimulation be considered for the treatment of peripheral diabetic neuropathy, based on one study.¹¹

MEDICAL POLICY	Percutaneous Neuromodulation Therapy (PNT) (All Lines of Business except Medicare)
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American College of Occupational and Environmental Medicine (ACOEM)

The 2020 evidence based guideline from the ACOEM for non-invasive and minimally invasive management of low back disorders did not recommend the use of percutaneous electrical nerve stimulation. The guidelines state:

“All of the following are Not Recommended (I), Low Confidence: microcurrent electrical stimulation, neuromuscular electrical stimulation (non-chronic pain), and percutaneous electrical nerve stimulation (PENS). There is No Recommendation (I), Low Confidence for or against all of: H-Wave1 Device stimulation therapy, high-voltage galvanic therapy, interferential therapy, and neuromuscular electrical stimulation (chronic LBP, chronic radicular pain).”¹²

National Institute for Health and Care Excellence (NICE)

In 2013, NICE published guidance on percutaneous electrical nerve stimulation for refractory neuropathic pain. The guidance states, “Current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.”¹⁴

POLICY SUMMARY

The current evidence is insufficient to determine the safety of efficacy of percutaneous neuromodulation therapy (PNT/PENS/PNS) as a treatment of any condition. High-quality, long-term randomized trials comparing this treatment to standard of care treatments are required. In addition, no evidence-based clinical practice guidelines were identified which recommend use of PNT as a treatment for any condition, including low back pain.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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MEDICAL POLICY**Percutaneous Neuromodulation
Therapy (PNT) (All Lines of Business
except Medicare)**

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