Medical Coverage Policy | Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

EFFECTIVE DATE: 02|01|2024
POLICY LAST REVIEWED: 11|18|2026

OVERVIEW
Percutaneous electrical nerve stimulation (PENS), percutaneous neuromodulation therapy (PNT), and restorative neurostimulation therapy (ReActiv8) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. Percutaneous electrical nerve stimulation is performed with needle electrodes while PNT uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue. ReActiv8 is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Restorative neurostimulation therapy (ReActiv8), Percutaneous electrical neurostimulation (PENS) or percutaneous neuromodulation therapy (PNT) for the treatment of chronic pain conditions is considered medically necessary if pain is effectively controlled by percutaneous stimulation and implantation of electrodes is warranted.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products
Restorative neurostimulation therapy (ReActiv8), Percutaneous electrical neurostimulation (PENS) or percutaneous neuromodulation therapy (PNT) for the treatment of chronic pain conditions is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery or not medically necessary benefits/coverage.

BACKGROUND
A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, present a substantial burden to patients, adversely affecting function and quality of life. Certain racial and ethnic groups are at a higher risk of developing diabetes, which may also put them at higher risk of developing complications from diabetes, such as diabetic neuropathy. According to a 2018 to 2019 National Health Interview Survey and data from the Indian Health Service National Data Warehouse, American Indians and Alaska Natives had the highest reported rate of diagnosed diabetes at 14.5%. This was followed by 12.1% of Black individuals, 11.8% of

Hispanic individuals, 9.5% of Asian individuals, and 7.4% of White individuals having diagnosed diabetes in 2018 or2019.

These chronic pain conditions have typically failed other treatments, and percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated as treatments to relieve unremitting pain.

Percutaneous electrical nerve stimulation is similar in concept to transcutaneous electrical nerve stimulation (TENS) (see evidence review 1.01.09) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. Percutaneous electrical nerve stimulation is generally reserved for patients who fail to get pain relief from TENS. Percutaneous electrical nerve stimulation is also distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS, the location of stimulation is determined by proximity to the pain.

Percutaneous neuromodulation therapy is a variant of PENS in which fine filament electrode arrays are placed near the area causing pain. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C fibers, thus preventing action potential propagation along the pain pathway.

The purpose of restorative neurostimulation therapy in individuals with chronic pain conditions is to provide a treatment option that is an alternative to or an improvement on existing therapies. The ReActiv8 System is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

Medicare Advantage Plans
PENS, which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

Commercial Products
For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia) who receive PENS, the evidence includes primarily small controlled trials and 2 systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review concluded that PENS could decrease pain intensity but not related disability, while the other found no significant differences between PENS and TENS in mitigation of pain. These conclusions are uncertain due to important methodological limitations in individual trials included in these reviews, such as high heterogeneity with regard to application methods. In the highest quality trial of PENS conducted to date in chronic low back pain, no difference in outcomes was found between the active (30 minutes of stimulation with 10 needles) and the sham (5 minutes of stimulation with 2 needles) treatments. Smaller trials, which have reported positive results, are limited by unclear blinding and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions (eg, knee osteoarthritis) who receive PNT, the evidence consists of a randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The single trial is limited by lack of investigator blinding, unclear participant blinding, and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions including low back pain who receive restorative neurostimulation therapy (ReActiv8), the evidence includes 1 sham-controlled RCT (N = 204), 1 prospective

single-arm trial (N = 53), and a case series (N = 44). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the RCT, there was no difference between groups on the primary endpoint of treatment response at 120 days, defined as the composite of 30% or greater reduction in VAS and no increase in pain medications (57.1% intervention vs 46.6% sham; p =.1377). Prespecified secondary analyses of primary outcome data favored the intervention group, but clinical significance is unclear. An uncontrolled follow-up phase of the RCT reported continued improvement in pain scores through 3 years but results are at high risk of bias due to lack of a control group and high attrition. Nonrandomized studies are limited by lack of blinding, no sham control, high attrition. and small sample sizes. Additional evidence from longer-term sham-controlled RCTs is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

There is not a specific code for PENS or PNT. Use the unlisted code below

64999 Unlisted procedure, nervous system

RELATED POLICIES

Lysis of Epidural Adhesions
Nerve Graft with Radical Prostatectomy
Occipital Nerve Stimulation – Insertion
Peripheral Subcutaneous Field Stimulation
Pulsed Radiofrequency for the Treatment of Chronic Pain
Sphenopalatine Ganglion Block for Headache
Unlisted Procedures

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REFERENCES

1. Food & Drug Administration. 2020. ReActiv8 Implantable Neurostimulation System. Approval Order. https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021A.pdf. Accessed January 20, 2026.
2. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. Jan 2005; 113(1-2): 9-19. PMID 15621359
3. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. Feb 2008; 9(2): 105-21. PMID 18055266
4. Gewandter JS, Dworkin RH, Turk DC, et al. Research design considerations for chronic pain prevention clinical trials: IMMPACT recommendations. Pain. Jul 2015; 156(7): 1184-1197. PMID 25887465
5. Plaza-Manzano G, Gómez-Chiguano GF, Cleland JA, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. Eur J Pain. Jul 2020; 24(6): 1023-1044. PMID 32171035
6. Beltran-Alacreu H, Serrano-Muñoz D, Martín-Caro Álvarez D, et al. Percutaneous Versus Transcutaneous Electrical Nerve Stimulation for the Treatment of Musculoskeletal Pain. A Systematic Review and Meta-Analysis. Pain Med. Aug 01 2022; 23(8): 1387-1400. PMID 35167691
7. Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. Mar 03 1999; 281(9): 818-23. PMID 10071003

8. Ghoname ES, Craig WF, White PF, et al. The effect of stimulus frequency on the analgesic response to percutaneous electrical nerve stimulation in patients with chronic low back pain. Anesth Analg. Apr 1999; 88(4): 841-6. PMID 10195535
9. Hamza MA, Ghoname EA, White PF, et al. Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain. Anesthesiology. Dec 1999; 91(6): 1622-7. PMID 10598602
10. Weiner DK, Rudy TE, Glick RM, et al. Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults. J Am Geriatr Soc. May 2003; 51(5): 599-608. PMID 12752833
11. Topuz O, Ozfidan E, Ozgen M, Ardic F. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskeletal Rehabil. 2004;17:127-133.
12. Yokoyama M, Sun X, Oku S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. Anesth Analg. Jun 2004; 98(6): 1552-1556. PMID 15155304
13. Weiner DK, Perera S, Rudy TE, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain. Nov 30 2008; 140(2): 344-357. PMID 18930352
14. Perez-Palomares S, Olivan-Blazquez B, Magallon-Botaya, et al. Percutaneous electrical nerve stimulation versus dry needling: effectiveness in the treatment of chronic low back pain. J Musculokeletal Pain. 2010;18:23-30.
15. Weiner DK, Rudy TE, Morone N, et al. Efficacy of periosteal stimulation therapy for the treatment of osteoarthritis-associated chronic knee pain: an initial controlled clinical trial. J Am Geriatr Soc. Oct 2007; 55(10): 1541-7. PMID 17908057
16. Weiner DK, Moore CG, Morone NE, et al. Efficacy of periosteal stimulation for chronic pain associated with advanced knee osteoarthritis: a randomized, controlled clinical trial. Clin Ther. Nov 2013; 35(11): 1703-20.e5. PMID 24184053
17. da Graca-Tarragó M, Deitos A, Patrícia Brietzke A, et al. Electrical Intramuscular Stimulation in Osteoarthritis Enhances the Inhibitory Systems in Pain Processing at Cortical and Cortical Spinal System. Pain Med. May 01 2016; 17(5): 877-891. PMID 26398594
18. Elbadawy MA. Effectiveness of Periosteal Stimulation Therapy and Home Exercise Program in the Rehabilitation of Patients With Advanced Knee Osteoarthritis. Clin J Pain. Mar 2017; 33(3): 254-263. PMID 27513639
19. Dunning J, Butts R, Henry N, et al. Electrical dry needling as an adjunct to exercise, manual therapy and ultrasound for plantar fasciitis: A multi-center randomized clinical trial. PLoS One. 2018; 13(10): e0205405. PMID 30379937
20. da Graca-Tarragó M, Lech M, Angoleri LDM, et al. Intramuscular electrical stimulus potentiates motor cortex modulation effects on pain and descending inhibitory systems in knee osteoarthritis: a randomized, factorial, sham-controlled study. J Pain Res. 2019; 12: 209-221. PMID 30655690
21. León-Hernández JV, Martín-Pintado-Zugasti A, Frutos LG, et al. Immediate and short-term effects of the combination of dry needling and percutaneous TENS on post-needling soreness in patients with chronic myofascial neck pain. Braz J Phys Ther. Jul 11 2016; 20(5): 422-431. PMID 27410163
22. Sumen A, Sarsan A, Alkan H, et al. Efficacy of low level laser therapy and intramuscular electrical stimulation on myofascial pain syndrome. J Back Musculoskelet Rehabil. 2015; 28(1): 153-8. PMID 25061034
23. Medeiros LF, Caumo W, Dussán-Sarria J, et al. Effect of Deep Intramuscular Stimulation and Transcranial Magnetic Stimulation on Neurophysiological Biomarkers in Chronic Myofascial Pain Syndrome. Pain Med. Jan 2016; 17(1): 122-35. PMID 26408420
24. Botelho L, Angoleri L, Zortea M, et al. Insights About the Neuroplasticity State on the Effect of Intramuscular Electrical Stimulation in Pain and Disability Associated With Chronic Myofascial Pain Syndrome (MPS): A Double-Blind, Randomized, Sham-Controlled Trial. Front Hum Neurosci. 2018; 12: 388. PMID 30459575

25. Dunning J, Butts R, Young I, et al. Periosteal Electrical Dry Needling as an Adjunct to Exercise and Manual Therapy for Knee Osteoarthritis: A Multicenter Randomized Clinical Trial. Clin J Pain. Dec 2018; 34(12): 1149-1158. PMID 29864043
26. Yoshimizu M, Teo AR, Ando M, Kiyohara K, Kawamura T. Relief of chronic shoulder and neck pain by electro-acupuncture and transcutaneous electrical nervous stimulation: A randomized crossover trial. Med Acupunct 2012;24(2):97103.
27. Ng MM, Leung MC, Poon DM. The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation. J Altern Complement Med. Oct 2003; 9(5): 641-9. PMID 14629842
28. Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial. Acupunct Med. Dec 2002; 20(4): 175-80. PMID 12512791
29. Cheng RSS, Pomeranz B. Electrotheraphy of chronic musculoskeletal pain: Comparison of electroacupuncture and acupuncture-like transcutaneous electrical nerve stimulation. Cochrane Library. Clin J Pain 1986;2(3):1439.
30. Lehmann TR, Russell DW, Spratt KF, et al. Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients. Pain. Sep 1986; 26(3): 277-290. PMID 2946016
31. Ghoname EA, White PF, Ahmed HE, et al. Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica. Pain. Nov 1999; 83(2): 193-9. PMID 10534590
32. White PF, Craig WF, Vakharia AS, et al. Percutaneous neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response?. Anesth Analg. Oct 2000; 91(4): 949-54. PMID 11004055
33. Hamza MA, White PF, Craig WF, et al. Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain. Diabetes Care. Mar 2000; 23(3): 365-70. PMID 10868867
34. Ahmed HE, White PF, Craig WF, et al. Use of percutaneous electrical nerve stimulation (PENS) in the short-term management of headache. Headache. Apr 2000; 40(4): 311-5. PMID 10759936
35. Raphael JH, Raheem TA, Southall JL, et al. Randomized double-blind sham-controlled crossover study of short-term effect of percutaneous electrical nerve stimulation in neuropathic pain. Pain Med. Oct 2011; 12(10): 1515-22. PMID 21883874
36. Kang RW, Lewis PB, Kramer A, et al. Prospective randomized single-blinded controlled clinical trial of percutaneous neuromodulation pain therapy device versus sham for the osteoarthritic knee: a pilot study. Orthopedics. Jun 2007; 30(6): 439-45. PMID 17598487
37. Bess S, Lafage V, Lorio M, et al. Multifidus Dysfunction and Chronic Low Back Pain: Systematic Review and Meta-analysis of the Supporting Data for Accurate Diagnosis and Successful Treatment Outcomes Associated With Restorative Neurostimulation. Int J Spine Surg. Dec 11 2025; 19(S3): S67-S84. PMID 41224648
38. Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. Oct 01 2021; 162(10): 2486-2498. PMID 34534176
39. Food & Drug Administration. 2020. ReActiv8 Implantable Neurostimulation System: Summary of Safety and Effectiveness Data. https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf. Accessed January 19, 2026.
40. Gilligan C, Volschenk W, Russo M, et al. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. Neuromodulation. Jan 2023; 26(1): 87-97. PMID 35088722
41. Gilligan C, Volschenk W, Russo M, et al. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. Neuromodulation. Jan 2023; 26(1): 98-108. PMID 36175320
42. Gilligan C, Volschenk W, Russo M, et al. Five-Year Longitudinal Follow-Up of Restorative Neurostimulation Shows Durability of Effectiveness in Patients With Refractory Chronic Low Back Pain Associated With Multifidus Muscle Dysfunction. Neuromodulation. Jul 2024; 27(5): 930-943. PMID 38483366
43. Schwab F, Mekhail N, Patel KV, et al. Restorative Neurostimulation Therapy Compared to Optimal Medical Management: A Randomized Evaluation (RESTORE) for the Treatment of Chronic

Mechanical Low Back Pain due to Multifidus Dysfunction. Pain Ther. Feb 2025; 14(1): 401-423. PMID 39812968
44. Smuck M, Lukes D, Schneider B, et al. Re-evaluation of categorial outcomes using common clinically relevant improvement thresholds following bilateral L2 medial branch restorative neurostimulation versus sham. Spine J. Dec 13 2025. PMID 41397571
45. Deckers K, De Smedt K, Mitchell B, et al. New Therapy for Refractory Chronic Mechanical Low Back Pain-Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. Neuromodulation. Jan 2018; 21(1): 48-55. PMID 29244235
46. Thomson S, Chawla R, Love-Jones S, et al. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. Pain Ther. Dec 2021; 10(2): 1451-1465. PMID 34478115
47. Mitchell B, Deckers K, De Smedt K, et al. Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain. Neuromodulation. Aug 2021; 24(6): 1024-1032. PMID 34242440
48. Ardeshiri A, Shaffrey C, Stein KP, et al. Real-World Evidence for Restorative Neurostimulation in Chronic Low Back Pain-a Consecutive Cohort Study. World Neurosurg. Dec 2022; 168: e253-e259. PMID 36184040
49. Bril V, England J, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy [RETIRED]: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. May 17 2011; 76(20): 1758-65. PMID 21482920
50. Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology. Jan 04 2022; 98(1): 31-43. PMID 34965987
51. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. Oct 02 2007; 147(7): 478-91. PMID 17909209
52. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. Apr 04 2017; 166(7): 514-530. PMID 28192789
53. Benzon HT, Connis RT, De Leon-Casasola OA, et al. 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. Apr 2010; 112(4): 810-33. PMID 20124882
54. Manchikanti L, Sanapati MR, Soin A, et al. Comprehensive Evidence-Based Guidelines for Implantable Peripheral Nerve Stimulation (PNS) in the Management of Chronic Pain: From the American Society Of Interventional Pain Physicians (ASIPP). Pain Physician. Nov 2024; 27(S9): S115-S191. PMID 39565237
55. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. J Pain Res. 2022; 15: 2483-2504. PMID 36039168
56. National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013; https://www.nice.org.uk/guidance/ipg450. Accessed January 20, 2026.
57. National Institute for Health and Care Excellence. 2022 Neurostimulation of lumbar muscles for refractory nonspecific chronic low back pain: Interventional Procedures Guidance. https://www.nice.org.uk/guidance/ipg739. Accessed January 20, 2026.
58. Centers for Medicare & Medicaid. National Coverage Determination (NCD) for Assessing Patient's Suitability for ELECTRICAL NERVE STIMULATION Therapy (160.7.1). 2006; https://www.cms.gov/medicare-coverage- database/details/ncd-details.aspx?NCDId=63&ncdver=2&CoverageSelection=National&KeyWord=Electrical+Nerve+Stimulation&Key WordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAABAAAAAA&. Accessed January 20, 2026.

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