

Via Email

September 17, 2026

BlueCross BlueShield Association
healthtechnologysubmissions@bcbsa.com

Re: Comment on Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain

Dear Health Technology Committee,

On behalf of the **North American Neuromodulation Society (NANS)**, we appreciate the opportunity to provide clinical and scientific input regarding BlueCross BlueShield Association's review of the clinical evidence and development of a model policy for Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain. We respectfully submit these comments for consideration by your team as you conduct your upcoming policy review.

NANS is a multidisciplinary professional society representing clinicians and scientists specializing in neuromodulation therapies for the treatment of chronic pain and neurologic disorders. Our membership includes leaders in clinical research, guideline development, and real-world implementation of neuromodulation technologies. Based on the totality of available evidence, NANS believes that contemporary PNS meets accepted standards for medical necessity and should no longer be considered investigational. Including PNS as an accepted therapy will give patients and providers one more option to consider when looking at ways to treat chronic pain.

PNS as a Medically Necessary Neuromodulation Therapy

Peripheral nerve stimulation has evolved substantially over the past decade. Modern PNS systems are FDA-cleared, minimally invasive, reversible, and supported by high-quality clinical evidence, including multiple randomized controlled trials. These systems are now routinely integrated into evidence-based pain care pathways for patients with chronic pain who have failed conservative management.

From a neuromodulation standpoint, PNS is distinct from historical electrical stimulation modalities. Contemporary systems are designed to modulate peripheral neural targets in a precise, titratable manner, producing meaningful reductions in pain and pain-related disability without permanent implantation or neural destruction. Importantly, PNS aligns with principles of graduated, stepwise care, often serving as an intermediate option prior to more invasive or permanent surgical interventions.

FDA-Cleared Peripheral Nerve Stimulation Systems in Current Clinical Use

It is important to note that PNS is not a single investigational technology, but rather a class of neuromodulation therapies with multiple FDA-cleared systems currently in routine clinical use. These include both temporary and implanted platforms that have undergone regulatory review for safety and effectiveness. Examples of FDA-cleared PNS systems include:

- **Freedom® PNS System (Curonix)** – a percutaneous implanted lead system with external power delivery, supported by Level I evidence demonstrating meaningful pain reduction and functional improvement.
- **Nalu™ Neurostimulation System (Nalu Medical)** – a miniaturized implanted PNS system powered externally, with prospective and randomized clinical evidence demonstrating significant improvements in pain and function.
- **SPRINT® PNS System (SPR Therapeutics)** – a temporary, 60-day percutaneous PNS system designed to deliver neuromodulation therapy without permanent implantation, supported by multiple randomized controlled trials demonstrating durable benefit beyond the treatment period.
- **StimRouter® and TalisMann™ PNS Systems (Bioventus)** – implanted lead-based systems with external components, supported by randomized controlled trial data and long-standing clinical use.

Restorative Neurostimulation

- **ReActiv8® (Mainstay Medical)** - ReActiv8 is also an FDA approved (2020) implantable peripheral nerve stimulation system that uses motor stimulation of the medial branch of the dorsal ramus to activate the lumbar multifidus and restore neuromuscular control. Importantly, restorative neurostimulation is a distinct form of implantable neuromodulation for a well-defined population of patients with mechanical chronic low back pain associated with lumbar multifidus dysfunction.

Collectively, these FDA-cleared systems reflect the technological maturity and diversity of the PNS landscape, allowing clinicians to tailor therapy to individual patient needs while maintaining consistent safety and efficacy standards.

Strength and Maturity of the Clinical Evidence

The PNS evidence base has reached a level of maturity that is inconsistent with an investigational designation.

Collectively, the literature now includes:

- More than a dozen randomized controlled trials, including sham-controlled and usual-care-controlled designs
- Extensive prospective, multicenter clinical studies
- Durable follow-up demonstrating sustained benefit beyond the active treatment period, particularly with temporary percutaneous systems

Across these studies, PNS has demonstrated:

- Statistically and clinically significant reductions in pain intensity
- Improvements in physical function and quality of life
- Reductions in pain interference and reliance on pharmacologic therapies

These outcomes are consistent across multiple pain etiologies and anatomic targets when patients are appropriately selected. We have included a list of studies and systematic reviews that support the safety and efficacy of PNS for treating chronic pain conditions. They are attached to this letter for your review.

The evidence base for restorative neurostimulation is also mature and includes two randomized controlled trials, including a head-to-head trial demonstrating superiority to optimal medical management, as well as long-term outcomes through five years, multiple real-world studies, and systematic reviews and meta-analyses. The 2026 ECRI Clinical Evidence Assessment rated ReActiv8 Favorable, and the 2026 AAPM Consensus Guidelines graded the evidence Grade A, High Certainty.

Safety

From a safety perspective, PNS compares favorably with alternative interventional pain treatments. Reported adverse events are predominantly mild, transient, and localized, such as skin irritation or temporary lead-related issues. Serious device-related complications and

permanent neurologic injury have not been observed in the peer-reviewed literature for FDA-cleared PNS systems.

Alignment with Professional Standards and Evolving Care Models

NANS recognizes that medical necessity determinations should reflect not only individual studies, but also consensus within the specialty community. PNS therapies are now formally recognized and endorsed within multiple professional society guidelines, including those developed by neuromodulation and pain-focused organizations. These guidelines consistently identify PNS as an evidence-based option for patients with chronic pain who have not achieved adequate relief with conservative therapies. Moreover, PNS supports broader healthcare objectives, including:

- Non-opioid pain management strategies
- Reduced reliance on long-term pharmacotherapy
- Potential avoidance or delay of more invasive surgical procedures

Medicare Coverage

In recent years, advancements in technology and a better understanding of the mechanisms behind nerve stimulation have significantly enhanced the safety and efficacy of this therapy. PNS devices are FDA-cleared and supported under both national and local Medicare coverage policies. Specifically, the National Coverage Determination (NCD) 160.7 affirms the medical necessity of implantable nerve stimulation for managing chronic pain. In addition, Local Coverage Determination (LCD) L34328 explicitly outlines covered indications for PNS, reinforcing that this modality is recognized as reasonable and necessary by Medicare ^{1,2}. PNS is also recognized as medically necessary by leading medical societies.

Alignment with other National Payers

Aetna recently changed its Peripheral Electrical Nerve Stimulation for Pain, adding coverage to peripherally implanted nerve stimulators for treatment of members with intractable neuropathic pain when criteria are met. NANS encourages BCBSA to consider following Aetna's recent change and extend the same coverage to their members.

¹ LCD 34328 – Peripheral Nerve Stimulation. Centers for Medicare & Medicaid Services.

(n.d.-a). Local coverage determination (LCD): Peripheral nerve stimulation (PNS) (LCD ID: L34328). U.S. Department of Health & Human Services.

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34328&ver=40>

² NCD 160.7 – Electrical Nerve Stimulators. Centers for Medicare & Medicaid Services.

(n.d.-b). *National coverage determination (NCD) for electrical nerve stimulators (160.7)*.

U.S. Department of Health & Human Services. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?ncdid=240&ncdver=1>

In addition, restorative neurostimulation is covered for appropriately selected patients by multiple commercial health plans, including Anthem, Highmark, and other Blue Cross Blue Shield plans. Medicare reimbursement is also established under Noridian coverage and billing guidance, with multiple Medicare Advantage plans following this approach.

Request for Policy

In light of the robust and expanding clinical evidence, established FDA clearance, favorable safety profile, and alignment with contemporary neuromodulation practice, NANS respectfully requests that Blue Cross Blue Shield Association (BCBSA) develop a model coverage policy that recognizes the Peripheral Nerve Stimulation therapies outlined above as medically necessary for appropriately selected patients with chronic pain. A positive model policy will set the foundation for your member plans to cover implantable peripheral nerve stimulation therapies to treat pain.

We also encourage the BCBSA to consider existing coverage determinations from other national and regional payers that already recognize the medical necessity of PNS, reflecting the current standard of care in this rapidly advancing field.

NANS would welcome the opportunity to engage in further dialogue with BCBSA's medical policy team to review the evidence in detail and discuss appropriate coverage criteria that ensure patient access while supporting responsible utilization.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Magdalena Anitescu', with a stylized, cursive script.

Magdalena Anitescu, MD, PhD
President, North American Neuromodulation Society

Notable PNS Studies and Papers

Abd-Elsayed A, Keith MK, Cao NN, et al. Temporary peripheral nerve stimulation as treatment for chronic Pain. *Pain Ther.* 2023;12(6):1415-1426.

Al-Jehani H, Jacques L. Peripheral nerve stimulation for chronic neurogenic pain. *Prog Neurol Surg.* 2011;24:27-40. doi: 10.1159/000323017. Epub 2011 Mar 21. PMID: 21422774.

Busch, Clayton, et al. "Peripheral Nerve Stimulation for Lower Extremity Pain." *Biomedicines* 10.7 (2022): 1666. <https://www.mdpi.com/1720372>

Chae, J., David, T.Y., Walker, M.E., Kirsteins, A., Elovic, E.P., Flanagan, S.R., & Fang, Z.P. (2005) [Intramuscular electrical stimulation for hemiplegic shoulder pain: a 12-month follow-up of a multiple-center, randomized clinical trial](#). *American journal of physical medicine & rehabilitation*, 84(11), 832-842.

Chih-Peng Lin, MD, PhD, Ke-Vin Chang, MD, PhD, Wei-Ting Wu, MD, Levent Özçakar, MD, *Ultrasound-Guided Peripheral Nerve Stimulation for Knee Pain: A Mini-Review of the Neuroanatomy and the Evidence from Clinical Studies*, *Pain Medicine*, Volume 21, Issue Supplement_1, August 2020, Pages S56–S63, <https://doi.org/10.1093/pm/pnz318>

Chitneni A, Berger AA, Orhurhu V, Kaye AD, Hasoon J. Peripheral Nerve Stimulation of the Saphenous and Superior Lateral Genicular Nerves for Chronic Pain After Knee Surgery. *Orthop Rev (Pavia)*. 2021 May 31;13(2):24435. doi: 10.52965/001c.24435. PMID: 34745463; PMCID: PMC8567809. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8567809/>

Colini Baldeschi, Gianni, et al. "Peripheral nerve stimulation in the treatment of chronic pain syndromes from nerve injury: a multicenter observational study." *Neuromodulation: Technology at the Neural Interface* 20.4 (2017): 369-374. https://www.neurimpulse.com/pubblicazioni/pubbb_8.pdf

Dabby R, Sadeh M, Goldberg I, Finkelshtein V. Electrical stimulation of the posterior tibial nerve reduces neuropathic pain in patients with polyneuropathy. *J Pain Res.* 2017 Nov 29;10:2717-2723. doi: 10.2147/JPR.S137420. PMID: 29238215; PMCID: PMC5716322. <https://pubmed.ncbi.nlm.nih.gov/29238215/>

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. *Pain Physician*: September/October 2020 23:E461-E474 E474 www.painphysicianjournal.com

Deer TR, Eldabe S, Falowski SM, Huntoon MA, Staats PS, Cassar IR, Crosby ND, Boggs JW. Peripherally Induced Reconditioning of the Central Nervous System: A Proposed Mechanistic Theory for Sustained Relief of Chronic Pain with Percutaneous Peripheral Nerve Stimulation. *J Pain Res.* 2021 Mar 12;14:721-736.

Goree JH, Grant SA, Dickerson DM, et al. Randomized placebo-controlled trial of 60-day percutaneous peripheral nerve stimulation treatment indicates relief of persistent postoperative pain, and improved function after knee replacement. *Neuromodulation.* 2024;27(5):847-861.

Latif U, Moghim R, Valimahomed A, et al. Consensus guidelines for the use of peripheral nerve stimulation in the treatment of chronic pain and neurological diseases: A neuron project from the American Society of Pain and Neuroscience. *J Pain Res.* 2025;18:5949-5990.

McGreevy K, McGreevy K. Peripheral nerve stimulation uses high-frequency electromagnetic technology to power an implanted neurostimulator with a separate receiver for the treatment of chronic pain in the lower extremities. *Pain Physician.* 2024;27(4):223-227.

Parikh S, Echevarria AC, Cemenski BR, Small T. The relevance of implanted percutaneous electrical nerve stimulation in orthopedics surgery: A systematic review. *J Clin Med.* 2024;13(13):3699.