Position Statement

Peripheral Nerve Stimulation Is Medically Necessary and Clinically Validated and Can No Longer Be Deemed Experimental

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Disclaimer: There was no external funding in the preparation of this article.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 03-20-2026
Accepted for publication: 5-30-2026

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Peripheral Nerve Stimulation (PNS) is a well-established neuromodulation therapy with decades of clinical use, a substantial body of clinically validated, peer-reviewed evidence, and endorsement in multiple evidence-based professional guidelines, including by the US Department of Defense. Despite this maturity, many commercial payers continue to deny coverage by categorizing PNS as "investigational" or "experimental," often conflating it with fundamentally different, indirect electrical stimulation modalities. This misclassification is increasingly misaligned with current science, clinical practice, and health-economic data, and has become a primary barrier to patient access to medically necessary care for refractory chronic pain. Given this extensive evidence base, it is no longer appropriate or ethical for payors to deny patients access to such an impactful treatment that clinicians and patients rely upon for managing refractory chronic pain.

The present position statement – peripheral nerve stimulation is medically necessary and clinically validated, is developed by consensus of multidisciplinary experts with deep expertise in the field of neuromodulation, chronic pain, and peripheral nerve stimulation. This position statement provides background and rationale showing the justification for the statement supported by literature research and clinical evidence.

Pain Physician 2026: 29:301-306

Peripheral nerve stimulation is increasingly recognized by professional medical societies and experts in interventional pain management and neuromodulation as a clinically validated, non-investigational treatment for chronic pain. A number of authors with multidisciplinary expertise in interventional pain management and neuromodulation and multiple professional medical societies have developed a position statement entitled "Peripheral nerve stimulation is medically necessary and clinically validated." Consequently, peripheral nerve stimulation is not investigational or experimental.

Peripheral nerve stimulation (PNS) is the targeted application of electrical impulses via implanted electrodes to specific named peripheral nerves for the treatment of chronic pain. It can also be used for a variety of other medical indications. PNS is distinct from other similarly named but indirect stimulation therapies that require less surgical and interventional expertise (indirect peripheral nerve field stimulation [PNfS], indirect percutaneous electrical nerve stimulation [PENS], PENS-Field Stimulation [PENFS], and transcutaneous electrical nerve stimulation [TENS]) (1-3).

In the 1960s, Wall and Sweet translated decades of

foundational scientific observations into clinical practice by implanting peripheral nerve stimulators to treat refractory pain (4). Early procedures were necessarily invasive, requiring open surgical exposure to directly visualize the target nerve. Electrodes were commonly coiled around or sutured to the nerve itself with a graft of fascia to "pad' the nerve to reduce direct electrical contact. While innovative for their time, these techniques were associated with surgical morbidity and limited scalability. Moreover, early PNS systems frequently relied on electrodes originally designed for spinal cord stimulation that were adapted for peripheral use; these devices were not optimized for the unique anatomy, biomechanics, or stimulation requirements of peripheral nerves.

Despite these limitations, PNS was recognized early on as an effective therapy. As early as 1977, some in the medical community concluded that PNS was efficacious, noting that "Peripheral nerve stimulators are the most efficacious of the implantable devices" (5). This acknowledgment underscores that PNS did not originate as an experimental concept, but rather as a clinically grounded therapy that has continued to evolve with advancing technology.

Over subsequent decades, PNS has undergone substantial technological and procedural evolution, transforming from a surgically intensive intervention into a precise, image-guided therapy. Purpose-built PNS systems are now available, with leads, fixation strategies, and stimulation parameters specifically engineered for placement in the periphery to stimulate the peripheral nervous system. These advances have improved safety, durability, and therapeutic consistency, clearly distinguishing contemporary practice from any earlier iterations.

Equally transformative has been the widespread adoption of medical imaging for clinical procedures, including ultrasound and fluoroscopic guidance. High-resolution ultrasound enables real-time visualization of peripheral nerves and surrounding structures, allowing accurate percutaneous lead placement while minimizing procedural risk. Interventions that once required open surgical exposure can now be performed safely and reproducibly in minimally invasive settings. The routine use of ultrasound guidance has expanded access to PNS, enhanced patient safety, and improved procedural efficacy: the hallmarks of a mature therapeutic modality.

Modern PNS is further defined by the availability of multiple evidence-supported technological paradigms. One approach employs a miniaturized, fully implanted pulse generator (IPG) paired with a peripheral nerve lead, enabling continuous long-term PNS for chronic pain. A second approach utilizes a fully implanted lead and separately connected receiver powered by an external transmitter, enabling continuous long-term total body PNS for chronic pain. A third paradigm delivers percutaneous PNS over a short-term period, delivered over approximately 60 days, in order to produce durable pain relief that persists after PNS lead removal (6). This latter approach challenges traditional assumptions that neuromodulation must be permanent to be effective and is supported by a growing body of evidence demonstrating sustained clinical benefit following device removal. The coexistence of these distinct yet validated strategies of PNS reflects therapeutic maturity rather than investigational uncertainty.

Evidence Base and Clinical Validation

These technological advances have occurred in parallel with expanding evidence base. The contemporary literature includes a substantial number of high-quality, peer-reviewed studies evaluating PNS across a wide range of pain conditions, including post-surgical pain, neuropathic pain, complex regional pain syndrome, hemiplegic shoulder pain, chronic low back pain, and other types of axial and appendicular musculoskeletal pain (7-18). This body of evidence includes multiple prospective randomized controlled trials (RCTs), including sham-controlled studies and comparisons to usual care with standard interventional management, an important methodological benchmark in neuromodulation research, demonstrating statistically and clinically meaningful improvements in pain, function, and quality of life (19-28). Numerous prospective non-randomized studies and extensive real-world evidence further support the safety, durability, and effectiveness of PNS in routine clinical practice (29-41).

Multiple systematic reviews (8,12-17) have shown predominantly positive, clinically definable results. Recent systematic reviews by Manchikanti et al (10) and D'Souza et al (8) showed positive evidence utilizing Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria. Manchikanti et al (10) evaluated 9 moderate to high quality trials and demonstrated moderate evidence and clinical applicability utilizing GRADE criteria. D'Souza et al (8) has evaluated implantable peripheral nerve stimulation for chronic pain with a systematic review and meta-analysis of analgesic outcomes up to 24 months. This was rather a large systematic review with 106 studies comprising

9,272 patients. The results showed that PNS was associated with large, statistically significant reductions in pain intensity from baseline to all time points: 3, 6, 12, and 24 months. In addition, subgroup analysis revealed no differences by study design or device type, while smaller effect sizes were reported in industry-funded studies and those with declared conflicts of interest.

Professional consensus has also evolved alongside the clinical data. Evidence-based clinical guidelines from multiple organizations, including the American Society of Interventional Pain Physicians (ASIPP), American Society of Pain and Neuroscience (ASPN), American Society of Regional Anesthesia and Pain Medicine (ASRA) and the U.S Department of Defense, now recommend the appropriate use of PNS in appropriately selected patients with chronic pain (2,10,11,42,43). Guideline inclusion reflects rigorous evaluation of the literature and expert consensus and represents a critical threshold in the transition from investigational therapy to accepted medical practice.

This evidence encompasses all available RCTs, including the study by Hayek et al (20), which evaluated peripheral nerve stimulation for the treatment of chronic craniofacial pain. Since then, a single randomized controlled trial was published by Billet et al (19).

Beyond clinical effectiveness, PNS has demonstrated economic value. Health-economic analyses, have shown cost dominance, with superior or equivalent clinical outcomes achieved at lower overall healthcare costs compared with conventional management (44-46). Large-scale insurance claims analyses further validate these findings, demonstrating reductions in total healthcare utilization following PNS implantation (47). In an era increasingly focused on value-based care, such outcomes strongly support the integration of PNS into standard treatment algorithms.

PNS has also been shown to confer opioid-sparing effects—an outcome of particular importance given the ongoing opioid epidemic. Published research indicates that integration of PNS into chronic pain treatment plans is associated with significant reductions in opioid consumption, improving individual patient safety while advancing broader public health goals (48,49).

Recommendations: Medical Necessity and Indications

Establishment of medical necessity and indications are crucial in performing any medical intervention, including peripheral nerve blocks and PNS. PNS trials or implants are required to meet the following:

1. Documented function-limiting moderate to severe pain for at least 3 months, with average pain scores of 5 or above
2. Documented failure of less invasive treatment modalities and medication of at least 4 weeks
3. Lack of surgical contraindications including infections and medical risks
4. Appropriate proper patient education, discussion and disclosure of risks and benefits
5. Lack of history of active substance abuse
6. Formal psychological screening by a qualified mental health professional
7. Successful stimulation trial with ≥ 50% reduction in pain intensity before permanent implantation

Evidence-Based Medicine and Policy Implications

It is important to recall that evidence-based medicine, as formally articulated by Sackett in the 1980s, was intended to integrate the best available evidence with clinical expertise and patient values to guide decision-making for individual patients and populations (50). This framework was designed to improve patient care, not to restrict access to proven therapies. In the payer environment, however, this principle has at times been distorted, used to justify denial of coverage for therapies perceived as novel or costly rather than evaluated on the totality of evidence.

Insurers retain the authority to determine reimbursement policy. They do not, however, possess the authority to redefine scientific reality. Given decades of clinical experience, a substantial peer-reviewed evidence base derived from randomized controlled trials and systematic reviews, extensive real-world outcomes, purpose-built technologies, safer and more precise procedural techniques, favorable health-economic analyses, opioid-sparing benefits, and endorsement in professional clinical guidelines, it is no longer scientifically defensible to characterize PNS as "investigational" or "experimental." This conclusion should lead to defined parameters and guidance for payment of PNS in appropriate candidates.

PNS is medically necessary in appropriately selected patients with refractory chronic pain. Continued misclassification risks denying effective, evidence-based, and cost-conscious care to individuals who stand to benefit. The evolution of PNS from open surgical experimentation to precision-guided, evidence-supported therapy clearly marks its arrival as a mature modality within modern pain medicine. Policy and coverage determinations must now reflect that reality.

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