

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

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Cigna

Medical Policy Department

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Re: Clinical Input Regarding Cigna's Peripheral Nerve Stimulation (PNS) Medical Coverage Policy #0539
— Scheduled Review March 15, 2026

Dear Members of the Cigna Medical Policy Team:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), we appreciate the opportunity to offer clinical perspective on the upcoming review of Cigna's Peripheral Nerve Stimulation (PNS) policy. Established in 1998, ASIPP is a non-profit professional organization that currently has a membership of over 4,500 interventional pain physicians and other practitioners. Its mission is to promote safe, appropriate, fiscally neutral and effective pain management services for patients nationwide who grapple with chronic and acute pain. The United States is home to approximately 8,500 proficient physicians with the requisite training and qualifications in interventional pain management. ASIPP is composed of 49 state societies of Interventional Pain Physicians, encompassing Puerto Rico, and includes the affiliated Texas Pain Society.

We also presented on October 7, 2025, ASIPP's position to HCSC Policy Review (1).

As Cigna reevaluates its position on PNS, we respectfully submit updated clinical evidence and national practice-level experience supporting the role of modern PNS therapies as medically necessary options for appropriately selected individuals.

OVERVIEW OF PNS AS AN ESTABLISHED INTERVENTIONAL MODALITY

Peripheral Nerve Stimulation (PNS) is a well-established neuromodulation therapy with decades of clinical use, a substantial body of robust, peer-reviewed evidence, and endorsement in evidence-based professional guidelines (2-6). Despite this maturity, many 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 barrier to patient access to medically necessary care for refractory chronic pain. Given this evidence base, it is no longer acceptable for payers to deny access to such an impactful treatment that clinicians and patients rely upon for managing refractory chronic pain; no longer can anyone claim PNS is "investigational" or "experimental".

EVIDENCE BASE AND CLINICAL VALIDATION

These technological advances have occurred in parallel with an expanding evidence base. The contemporary literature includes a substantial number of 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 (2-6). 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. This evidence has been evaluated which included randomized controlled trials, as well as observational studies. As we have shown in our previous letter, ASIPPs evidence-based guidelines (5) published in 2024, included all companies providing peripheral nerve stimulation systems.

ASIPP has developed and published evidence-based guidelines in 2024 (5), which include all companies providing peripheral nerve stimulation systems.

- Freedom® Peripheral Nerve Stimulator (PNS) System (Curonix LLC, 2017)
- StimRouter® Neuromodulation System (Bioness, now Bioventus, 2015)
- SPRINT® PNS System (SPR® Therapeutics, Inc., 2016)
- Nalu™ Neurostimulation System (Nalu Medical Inc., 2019)

These guidelines were developed in accordance with the technology evaluation criteria for new technologies established by the National Committee for Quality Assurance (NCQA), with all criteria appropriately met. The following five criteria were evaluated:

- The PNS technology must have final clearance or approval from the appropriate governmental regulatory bodies
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
- Technology must improve the net health outcome. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes
- Technology should improve the net health outcome as much as, or more than, established alternatives
- The improvement must be attainable outside the investigational settings

The guideline development process convened a multidisciplinary panel of experts across medical and pharmaceutical specialties under ASIPP's direction. This panel systematically reviewed the evidence, considered patient perspectives, and formulated recommendations for the use of implantable peripheral nerve stimulation (PNS) in chronic pain management.

Importantly, the methodology incorporated the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework, along with rigorous methodological quality assessment of evidence and recommendations, following a modified approach established by ASIPP.

A systematic review and meta-analysis of randomized controlled trials (RCTs) by Manchikanti et al (6) evaluated nine RCTs (7-15), including seven high-quality and two moderate-quality studies based on Cochrane Review Criteria, and nine moderate-quality studies based on IPM-QRB criteria. Using GRADE methodology, seven of nine studies demonstrated moderate evidence and clinical applicability, while two of nine showed low evidence and applicability. The systematic review also incorporated a comprehensive meta-analysis.

The evidence synthesized in the guidelines and systematic review (5,6) indicated the following:

Overall, the combined qualitative and quantitative analyses supported a **fair, Level III evidence** rating with **moderate certainty** and a **moderate strength of recommendation** for:

- Implantable PNS systems following a trial or selective lumbar medial branch stimulation without a trial
- Temporary PNS therapy for 60 days

This evidence encompasses all available RCTs, including the study by Hayek et al (7), which evaluated peripheral nerve stimulation for the treatment of chronic craniofacial pain.

The comprehensive, evidence-based guidelines for implantable PNS in chronic pain management also provided a summary of recommendations that included both evidence synthesis and additional clinical considerations, as outlined below:

- Based on the evidence and the recommendations, indications may be expanded from present CMS guidance with addition of craniofacial pain, phantom limb pain, and low back pain, either nociceptive or neuropathic, with present evidence showing Level III or fair with moderate certainty utilizing GRADE criteria.

Evidence Level: Fair; Strength of Recommendation: Moderate

- It is important to understand each type of peripheral nerve stimulation implant with features of the equipment and technical requirements.

Evidence Level: Moderate; Strength of Recommendation: Strong

- Based on the available evidence and all the available guidance, patient education is a crucial aspect of success of peripheral nerve stimulation.

Evidence Level: Moderate; Strength of Recommendation: Strong

- Risk stratification of peripheral nerve stimulation, based on ASIPP guidelines: low risk for peripheral nerve stimulation trial and implantation of extremities and other superficial nerves, moderate risk for lumbar medial branches and high risk for thoracic and cervical medial branches, trigeminal and cranial nerve blocks and nerve stimulation.

Evidence Level: Moderate; Strength of Recommendation: Moderate

In addition to that, more recently, a systematic review published by D'Souza et al (3) 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 9272 patients. The results showed that PNS was associated with large, statistically significant reductions in pain intensity from baseline to all time points: 3 months, 6 months, 12 months, 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. However, criticism may be advanced against this systematic review and meta-analysis as GRADE criteria was rated as low for the primary outcome, due to pooling from observational studies, risk of bias, and heterogeneity.

Beyond clinical efficacy, 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 (16-18). Large-scale insurance claims analyses further validate these findings, demonstrating reductions in total healthcare utilization following PNS implantation (19). 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 (20,21).

REQUEST FOR POLICY REVISION

Given the evidence, favorable long-term outcomes, and alignment with professional society guidelines, we respectfully request that Cigna:

1. Reconsider the “not medically necessary” designation for Peripheral Nerve Stimulation.
2. Update Policy #0539 to reflect PNS as medically necessary for appropriate indications.
3. Consider precedents from other payers such as Aetna, BCBS Alabama, and Medicare MACs.

ASIPP welcomes the opportunity to discuss these data further and provide additional clinical insights during your policy review.

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