NANS
NORTH AMERICAN NEUROMODULATION SOCIETY

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Cigna Medical Policy Committee
Via email: medical.policy-reviewrequest@cigna.com

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Re: Comment on Cigna Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation – Medical Coverage Policy 0539 (Scheduled Review: March 15, 2026)

Dear Medical Policy Committee,

On behalf of the North American Neuromodulation Society (NANS), we appreciate the opportunity to provide clinical and scientific input regarding Cigna's medical policy on Peripheral Nerve Stimulation (PNS), which currently classifies this therapy as not medically necessary. We respectfully submit these comments in advance of the upcoming March 15, 2026, 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.

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.

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 percutaneous 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 is 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

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Request for Policy Reconsideration

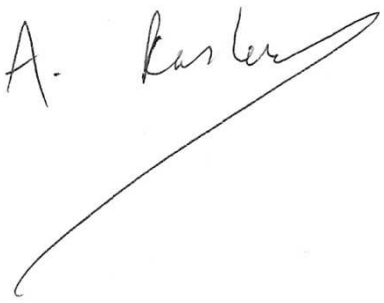
In light of the robust and expanding clinical evidence, established FDA clearance, favorable safety profile, and alignment with contemporary neuromodulation practice, NANS respectfully requests that Cigna revise Medical Policy 0539 to recognize Peripheral Nerve Stimulation as medically necessary for appropriately selected patients with chronic pain.

We also encourage Cigna 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 Cigna'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,



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