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Society of Interventional Radiology
The vision to heal

February 11, 2026

Amy Flaster, MD
Chief Medical Officer
Cigna Healthcare
900 Cottage Grove Road
Bloomfield, Connecticut 06002

Submitted via: medical.policy-reviewrequest@cigna.com

Re: Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation – Medical Coverage Policy 0539

Dear Dr. Flaster,

The Society of Interventional Radiology (SIR) appreciates the opportunity to provide comments on the medical coverage policy 0539 for peripheral nerve stimulation and peripheral nerve field stimulation. As a medical specialty society representing over 8,000 members, including U.S. physicians practicing in vascular and interventional radiology, SIR represents physicians specializing in minimally invasive, image-guided therapies used to diagnose and treat a wide range of conditions, including chronic pain. Our members routinely perform percutaneous nerve-targeted interventions and are directly involved in patient selection, procedural execution, and post-procedural outcomes. Based on current evidence and clinical experience, SIR believes that **peripheral nerve stimulation meets accepted standards of medical necessity when used in appropriately selected patients with chronic pain**.

PNS as an Image-Guided, Minimally Invasive Therapy

Peripheral nerve stimulation is fundamentally aligned with the principles of interventional radiology. Contemporary PNS systems are placed using **image-guided, percutaneous techniques**, allowing precise localization of targeted peripheral nerves while minimizing tissue disruption.

For patients with chronic pain who have failed conservative management, PNS provides a **minimally invasive alternative to surgical intervention** and offers an option. From a procedural standpoint, PNS enables tailored therapy with limited procedural risk and rapid recovery, characteristics that are consistent with evidence-based interventional practice.

FDA-Cleared PNS Systems in Current Clinical Use

Peripheral nerve stimulation is not experimental. Multiple **FDA-cleared PNS systems are currently used in routine clinical practice**, encompassing both temporary and implanted technologies that have undergone regulatory review for safety and effectiveness. Examples include:

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

The availability of multiple FDA-cleared platforms allows clinicians to select an approach based on anatomy, pain etiology, and procedural considerations while maintaining consistent safety standards.

Clinical Evidence and Procedural Outcomes

The clinical evidence supporting PNS includes **multiple randomized controlled trials**, prospective multicenter studies, and real-world clinical experience. These data consistently demonstrate:

- Clinically meaningful reductions in pain intensity
- Improvements in physical function and daily activity
- Durable benefit beyond the active stimulation period, particularly with temporary percutaneous systems

From an interventional radiology perspective, these outcomes are significant because they demonstrate that PNS provides **lasting therapeutic benefit without requiring repeated invasive procedures or escalation to surgical care**.

Safety Profile and Risk Mitigation

PNS demonstrates a favorable safety profile when performed using image-guided techniques. Reported adverse events are generally **mild, localized, and self-limited**, such as transient skin irritation or minor lead-related issues. Serious complications and permanent neurologic injury have not been reported in the peer-reviewed literature for FDA-cleared percutaneous PNS systems.

Alignment with Interventional Standards of Care

SIR supports evidence-based, minimally invasive therapies aligned with appropriate use principles. Peripheral nerve stimulation meets these criteria and is increasingly incorporated into multidisciplinary pain management pathways to improve outcomes while reducing procedural risk and healthcare utilization.

Coverage of PNS supports broader healthcare objectives, including:

- Reduced need for surgical intervention
- Support of non-opioid pain treatment strategies
- Efficient use of image-guided, outpatient procedures

Request for Policy Reconsideration

In advance of the upcoming policy review, **SIR respectfully requests that Cigna revise Medical Policy 0539 to recognize Peripheral Nerve Stimulation as medically necessary for appropriately selected patients with chronic pain**.

We encourage Cigna to align its policy with the current evidence base, FDA regulatory status, and the evolving role of minimally invasive image-guided therapies in chronic pain management.

SIR appreciates the opportunity to provide meaningful feedback on Cigna's medical coverage policy and welcomes the opportunity to engage further with Cigna's medical policy team to review the evidence and discuss clinically appropriate coverage criteria. If you have any questions, please do not hesitate to contact SIR's Senior Manager of Health Policy and Economics, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Robert A. Lookstein, MD, FSIR
President, Society of Interventional Radiology

Cc: Eve Lee, MBA, CAE
Chief Executive Officer, Society of Interventional Radiology