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Re: Comment on Elevance Health Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation classification as “experimental & investigational.”

Dear Mr. London,

On behalf of the **American Academy of Pain Medicine (AAPM)**, thank you for the opportunity to provide comments regarding Elevance Health’s Peripheral Nerve Stimulation (PNS) medical policy, which currently classifies PNS as *experimental & Investigational*. We are concerned that the policy continues to classify peripheral nerve stimulation (PNS) as “experimental and investigational.” This characterization does not reflect the current state of scientific evidence, FDA clearances, clinical guidelines, payer precedent, or nationwide utilization.

AAPM is a national medical specialty society representing physicians and multidisciplinary clinicians dedicated to the diagnosis and treatment of acute, chronic, and cancer-related pain. Our members practice across academic, hospital-based, and community settings and are responsible for the longitudinal management of complex pain conditions. Based on current evidence and clinical experience, AAPM believes that **peripheral nerve stimulation represents a medically necessary and evidence-based treatment option for appropriately selected patients with chronic pain.**

The Need for Evidence-Based Non-Opioid Therapies

The opioid crisis has underscored the urgency of expanding access to non-opioid, evidence-based interventions. PNS represents precisely this type of therapy: minimally invasive, durable, and effective in reducing pain while restoring function. Patients who receive PNS frequently report reductions in pain interference with daily activities, improved mobility, and reduced dependence on medications. For many, PNS offers a pathway to recovery and a return to meaningful participation in work, family, and community life.

Clinical Evidence for PNS

The clinical literature supporting PNS is extensive and continues to expand:

- **13 randomized controlled trials** and more than **185 peer-reviewed publications** consistently show significant improvements in pain reduction, function, and quality of life.
- Multiple FDA-cleared devices—including the **SPRINT® PNS (SPR Therapeutics, Inc.)**, **Nalu Neurostimulation System (Nalu Medical, Inc.)**, and **StimRouter Neuromodulation System (Bioventus, LLC)** have each been evaluated in controlled clinical studies and real-world data sets demonstrating safety and efficacy.

Key highlights:

- *SPRINT® PNS*: Seven RCTs demonstrate clinically meaningful and durable pain and function improvements, with >70% of patients reporting benefit beyond the 60-day treatment period.
- *Nalu Neurostimulation*: The COMFORT RCT and registry evidence confirm long-term reductions in pain and improved quality of life at 6 and 12 months.
- *StimRouter*: The prospective, multicenter, randomized trial by Deer et al. (2016) demonstrated statistically significant improvements in neuropathic pain with no serious device-related adverse events.

Clinical Guidelines

Professional guidelines reinforce that PNS is an evidence-based therapy:

- **ASPN 2022 guidelines** recommended PNS for multiple neuropathic and musculoskeletal pain conditions.
- **ASIPP 2024 guidelines** issued strong recommendations for PNS based on Level I and II evidence.
- **ASPN 2025 Consensus Guidelines** for 60-day PNS affirmed durable functional improvement and pain relief beyond the treatment window.

These consensus statements make clear that PNS is part of the current standard of care.

Safety Profile

- **SPRINT® PNS**: Over 32,000 patients treated; serious adverse events in just 0.12%, most events being mild and transient.
- **Nalu Neurostimulation**: More than 7,500 implants with no serious device-related adverse events reported.
- **StimRouter**: No unanticipated or serious device-related adverse events reported in prospective studies.

This favorable safety profile is consistent across clinical trials and real-world use.

Payer Precedent

Several major payers have already adopted policies that recognize PNS as medically necessary:

- **Aetna** (*Electrical Stimulation for Pain*, Clinical Policy Bulletin No. 0011)
- **Blue Cross Blue Shield of Alabama** (*Peripheral Nerve Stimulation of the Trunk or Limbs for Treatment of Pain*, Policy No. 623)

- **Noridian Medicare LCD L34328** and associated coverage article

These policies provide clear models for evidence-based coverage that balances access with appropriate utilization criteria.

Conclusion

Given the **robust clinical evidence, favorable safety record, society guidelines, physician adoption, and national payer precedent**, AAPM respectfully urges Elevance Health to revise its draft policy to provide coverage for PNS in appropriately selected patients with chronic pain. Denying coverage perpetuates reliance on less effective, higher-risk therapies and restricts access to a proven, minimally invasive, non-opioid option that can restore function and improve lives.

AAPM stands ready to collaborate with Elevance Health and provide additional evidence, expert testimony, or participation in medical policy discussions to ensure your members have access to the best available pain management strategies.

Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Marie Hanna', with a horizontal line underneath.

Marie Hanna, MD, MEHP
President
American Academy of Pain Medicine (AAPM)

References

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