March 11, 2026

Medical Technology Assessment Committee
Blue Cross and Blue Shield of Minnesota
3535 Blue Cross Road
Eagan, MN 55122

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional pain and spine procedures to accurately diagnose and treat patients, are writing to express serious concerns regarding the *Peripheral Nerve Stimulation of the Trunk or Limbs for Treatment of Pain* policy. The policy indicates that peripheral nerve stimulation (PNS) is considered experimental, investigational, and/or unproven as a treatment for chronic pain. The failure to provide coverage for PNS procedures for chronic pain creates significant concern among the pain medicine societies, given the strong evidence that demonstrates the effectiveness of these procedures in the care of patients who suffer from chronic pain.

Peripheral nerve stimulation has been widely studied and utilized for over two decades, with increasing evidence supporting its effectiveness for patients suffering from conditions such as chronic migraines, neuropathic pain, and complex regional pain syndrome (CRPS). Numerous clinical trials and real-world studies have demonstrated that PNS can offer significant relief. Denying patients access to this minimally invasive PNS option will put patients at increased risk of escalating their opioid use or undergoing more invasive surgical procedures for phantom limb pain, neuropathic pain, and axial low back pain.

In recent years, advancements in technology and a better understanding of the mechanisms behind nerve stimulation have significantly enhanced the safety and efficacy of this therapy. PNS devices are FDA-cleared and supported under both national and local Medicare coverage policies. Specifically, the National Coverage Determination (NCD) 160.7 affirms the medical necessity of implantable nerve stimulation for managing chronic pain. In addition, Local Coverage Determination (LCD) L34328 explicitly outlines covered indications for PNS, reinforcing that this modality is recognized as reasonable and necessary by Medicare[1,2]. PNS is also recognized as medically necessary by leading medical societies. A comprehensive review[3] of 20 randomized controlled trials and 33 prospective observational studies identified Level I evidence supporting the efficacy of PNS for the treatment of:

- Chronic migraine headaches via occipital nerve stimulation
- Chronic hemiplegic shoulder pain via stimulation of nerves innervating the trapezius, supraspinatus, and deltoid muscles
- Failed back surgery syndrome via subcutaneous peripheral field stimulation
- Lower extremity neuropathic and lower extremity post-amputation pain via sciatic and/or femoral nerve stimulation

Moreover, the evidence supporting the clinical benefits of PNS continues to grow. Large-scale studies and peer-reviewed articles have documented its positive impact in treating various pain

conditions, with some studies reporting over 70% mean pain reduction in knee, shoulder, foot/ankle, and low back pain, along with significant functional improvement[4]. A 2024 study by Hatheway *et al.* randomized 58 patients to PNS therapy and 31 to a conservative medical management (CMM) arm[5]—a study design similar to those cited to support FDA approval of spinal cord and dorsal root ganglion stimulation. In this study, the PNS group reported a nearly 50% reduction in the Oswestry Disability Index and Beck Depression Index at one year, which is perhaps even more meaningful than the reported 69% reduction in pain. This evolving body of research, coupled with the success of PNS in clinical practice, demonstrates that PNS is no longer investigational or experimental.

The lack of serious adverse events seen with PNS is very important. Compared to other established surgical interventions, PNS has a particularly favorable risk profile, with lower rates of revisions or device-related complications, as documented in the literature.

We urge BCBSMN to review the most current literature and medical guidelines on PNS and consider revising the policy to reflect the evolving evidence that supports its use in managing chronic pain. By doing so, you would acknowledge the positive impact PNS has on patients' well-being and ensure that members have access to a proven, effective alternative to more invasive procedures and pain management strategies.

We greatly appreciate your consideration and look forward to a prompt response. If you require any additional information or would like to discuss this request further, please do not hesitate to contact Sarah Cartagena, Director of Health Policy at the International Pain and Spine Intervention Society, at scartagena@ipsismed.org. We are confident that, upon reviewing the available evidence, you will come to appreciate the value that PNS offers to individuals who are struggling with debilitating chronic pain.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American College of Radiology
American Society of Anesthesiologists
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society of Interventional Radiology

References:

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2. NCD 160.7 – Electrical Nerve Stimulators. Centers for Medicare & Medicaid Services. (n.d.-b). *National coverage determination (NCD) for electrical nerve stimulators (160.7)*. U.S. Department of Health & Human Services. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=240&ncdver=1
3. Coverage for StimRouter and implantable peripheral nerve stimulation for chronic pain conditions [PowerPoint slides]. Unpublished internal document. Attached via email.
4. Strand N, D'Souza RS, Hagedorn JM, Pritzlaff S, Sayed D, Azeem N, et al. (2022). Evidence-based clinical guidelines from the American Society of Pain and Neuroscience for the use of implantable peripheral nerve stimulation in the treatment of chronic pain. J Pain Res. 2022 Aug 23;15:2483-2504. doi: 10.2147/JPR.S362204. PMID: 36039168; PMCID: PMC9419727.
5. Hatheway J, Hersel A, Engle M, Gutierrez G, Khemlani V, Kapural L, et al. Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 12-month results from the COMFORT-randomized controlled trial. Reg Anesth Pain Med. 2024 Nov 20:rapm-2024-106099. doi: 10.1136/rapm-2024-106099. Epub ahead of print. PMID: 39572166.