New York Society of Interventional Pain Physicians

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NYSIPP POSITION STATEMENT

Percutaneous Peripheral Nerve Stimulation (PNS)

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Position Statement

The New York Society of Interventional Pain Physicians (NYSIPP) strongly supports the use of Peripheral Nerve Stimulation (PNS) for those patients with intractable neuropathic pain who have failed previous conservative and/or invasive modalities. Patients in this category have no credible alternatives. Based upon review of the body of peer reviewed published evidence, approval by the United States Food and Drug Administration (FDA), real world experience, and long term patient outcomes, NYSIPP recommends qualified physicians consider the use of this modality based upon clinical need and presentation. Because of proven safety and durable effectiveness, PNS systems are within the standard of care for their indicated use.

Based upon the body of peer-reviewed published evidence, FDA approval, recognition under a Medicare National Coverage Determination (160.7), and robust support from esteemed entities like the National Institutes of Health and the Department of Defense, NYSIPP further recommends policymakers and payers enable timely access to PNS when prescribed by a qualified physician who has used his or her best medical judgement in caring for those patients with focal neuropathic pain syndromes.

Background

Percutaneous Peripheral Nerve Stimulation (PNS) employs electrical pulses through small electrodes percutaneously implanted near targeted peripheral nerves, offering a non-opioid alternative for chronic pain since FDA approval in 2016. Temporary trial stimulation can be followed by permanent implantation when indicated. NYSIPP advocates for the use of PNS systems in managing chronic pain that persists after two or more conservative treatments have failed. The following devices hold FDA clearance for temporary and/or permanent implantation:

a. Freedom PNS System – Curonix
b. Nalu PNS System – Nalu Medical
c. SPRINT PNS System – SPR Therapeutics
d. StimRouter System – Bioventis

The first theme that must be addressed is the importance of providing patients who can benefit from PNS devices with access to these devices. PNS devices that have met rigorous requirements such as pre–market approval should be made available to patients who can benefit. Patients who have exhausted all conservative therapies and still suffer from pain should have access to these devices as a viable alternative.

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Next, the safety of PNS devices must be acknowledged. PNS devices have an established historical profile for safety (2,4). Additionally, it is important to note that PNS devices are not novel technologies, and their use has been validated in multiple clinical studies (2,3,4,5,6).

Finally, the application of neuromodulation, including PNS, has been shown to be a cost-effective option in the treatment of chronic pain compared to other treatment options. One study demonstrated reductions in physician office visits, nerve blocks, radiologic imaging, emergency department visits, hospitalizations, and surgical procedures. This translated to a net annual savings of c. $30,221 and a savings of $93,685 over the 3-year implant duration. The large reduction in healthcare utilization following spinal cord/peripheral nerve stimulation implantation resulted in a net per patient per year cost savings of approximately $17,903 (1).

Over 30 peer reviewed publications, including randomized controlled trials (2,3), endorse the efficacy of PNS systems in managing pain of the shoulder, back, knee, foot, and other conditions including phantom limb pain. Clinical studies consistently demonstrate positive outcomes across neuropathic syndromes, further validating PNS as standard of care. The most recent randomized controlled study (RCT) across 14 pain management centers (COMFORT PNS RCT) demonstrated an 87% responder rate (>50% pain reduction) at one year (2,3). Categorizing this treatment as “experimental and investigational” is grossly inaccurate.

Conclusion and Recommendations

NYSIPP strongly advocates for the utilization of Percutaneous Peripheral Nerve Stimulation (PNS) by qualified, trained physicians for patients with focal neuropathic pain syndromes who have failed > 6 months of conservative therapy. The body of published evidence, long term outcomes demonstrating durable treatment effect, low complication rate, as well as cost effectiveness makes this an essential tool in the management of refractory neuropathic pain syndromes. Additionally, with the support of Medicare National Coverage Determinations and the National Institutes of Health, it has become the standard of care within the Pain Management community. Policymakers and payers are strongly encouraged to enable timely access to FDA approved technologies when deemed medically necessary and indicated.

References

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