Peripheral nerve stimulators for chronic nerve pain

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Policy contains: Peripheral nerve stimulator, chronic pain, radiculopathy, dermatomal distribution, musculo-skeletal pain, pain pathways, spinal cord stimulator, facet nerve pain

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Coverage policy

Peripheral nerve stimulators for chronic neuropathic pain are investigational/not clinically proven and, therefore, not medically necessary.

The Pain Management Best Practices Inter-Agency Task Force Report (2019) identifies gaps in established criteria-based guidelines for properly credentialing clinicians who are trained in using interventional techniques to help diagnose, treat, and manage patients with chronic pain as well as limited well researched guidelines for the appropriate timing of use for these interventions in combination with other modalities, and long term outcomes.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Alternative covered services may include rehabilitation therapy, peripheral nerve blocks, trigger point injections, facet joint injections, medication and surgical interventions, non-implantable stimulation devices, transcutaneous nerve stimulators, yoga, meditation, massage therapy, acupuncture, guided imagery as prescribed by primary care provider or pain specialist.

Background

According to the Centers for Disease Control and Prevention (CDC), 50 million adults in the United States have chronic daily pain, with 19.6 million adults experiencing high-impact chronic pain that interferes with daily life or work activities. The cost of pain to our nation is estimated at between $560 and $635 billion annually. At the same time, our nation is facing an opioid crisis that, over the past decade, has resulted in an unprecedented wave of overdose deaths associated with prescription opioids, heroin, and synthetic opioids.

Pain is defined as acute or chronic; characterized as an unpleasant feeling such as a prick, sting, tingle, burning, aching or vice like. It may be sharp or dull in nature; in one area or all over your body. Acute pain is a signal by the body in response to an illness or injury sustained (Trent, 2021). Chronic pain and it's sequelae is one of the leading causes of disability and mortality in the world. There are many definitions to what constitutes chronic pain but it is agreed that it is of long duration, persisting three to six months and beyond the usual recovery time period; it may be constant or intermittent in nature. The original cause may be an illness or injury, arthritis or cancer, and sometimes no known cause. It is affected by environmental and psychological factors (Trent, 2021).

Managing chronic pain remains a challenge due to the pain medicine model of pain management remains as first line therapy. The increasing opioid crisis and subsequent overdoses and deaths has led to the increased popularity of non-opioid analgesia and combining multimodal pain relieving interventional procedures such as spinal cord stimulators and peripheral nerve stimulators. The differences between the two are lead placement and treatment goals. Spinal cord stimulators (leads placed in the epidural space) are used more for long term chronic pain; and peripheral nerve stimulators (leads placed on peripheral nerve dermatome areas) for acute and chronic pain for a shorter time duration in most cases (Dydyk, 2021). In those who have contraindications to spinal cord stimulator placement, peripheral nerve simulators can provide lasting pain relief without the potential risks of pain medications. Peripheral nerve stimulators may be a preferred option over peripheral local anesthetic nerve blocks to avoid the undesirable motor weakness effects associated with it (Ilfeld, 2016).

Peripheral nerve stimulator indications include conditions that have neuropathic pain transmission located along a dermatomal distribution of the nerve (Appendix A) such as, but not limited to (Jain 2019, Trent 2021):

1) Median/ulnar/radial neuropathy (forearm, wrist, hand)
2) Occipital neuralgia (head, neck)
3) Cluneal nerve pain (low back-leg)
4) Pudendal neuralgia (pelvis, genitalia)
5) Femoral/sciatic/obturator neuropathy (upper, median thigh, leg)
6) Brachial/lumbar plexus neuropathy (chest, shoulder, arm, hand)
7) Meralgia paresthetica (outer thigh)
8) Lumbar/cervical radiculitis (low back, leg, buttocks, arm, chest)
9) Intercostal neuralgia (chest wall, upper trunk)

Findings

Conventional neurostimulation used for pain relief in the U.S. typically doesn't involve clinical trials or is assessed for just a brief period for efficacy prior to use. Percutaneous neurostimulation placement within peripheral nerves involves insertion of a lead wire through an introducer targeting the nerve plexus or motor point within a muscle. Electrical current via an external generator may then pass through the skin to the targeted area requiring treatment (Ilfeld, 2016).

According to American Society of Anesthesiologists (2010) guidelines for electrical stimulus neuromodulation; Observational study findings indicated that peripheral nerve stimulation can provide pain relief for assessment periods ranging from four months to two years. However, the guidelines site spinal cord stimulators as the preferred choice for chronic persistent radicular pain used in patients who have not responded to other therapies. It may also be considered for other selected patients (e.g., those with chronic regional pain syndrome, peripheral neuropathic pain, peripheral vascular disease, or post herpetic neuralgia). Shared decision making should include risks and potential complications associated with device placement and a spinal cord stimulator trial should be performed before considering permanent implantation (American Society of Anesthesiologists, 2010).

The Pain Management Best Practices Inter-Agency Task Force (Task Force) was convened by the U.S. Department of Health and Human Services (DHHS) in conjunction with the Department of Defense (DOD) and the Veterans Administration (VA) with the Office of National Drug Control Policy (ONDCP) to address acute and chronic pain care in light of the ongoing opioid crisis. The 29 member Task Force mandate was to identify gaps, inconsistencies, and updates, and to make recommendations for best practices for managing acute and chronic pain. They considered relevant medical and scientific literature and information provided by government and non-government experts in pain management, addiction, mental health and representatives from various disciplines; also reviewed and considered patient testimonials and public meeting comments, including approximately 6,000 comments from the public submitted during a 90-day public comment period and 3,000 comments from two public meetings (The Pain Management Best Practices Inter-Agency Task Force, 2019).

A case report demonstrates the results of short-term percutaneous peripheral nerve stimulation (PNS) in two chronic low back pain patients in which at the end of the 30 day therapy, stimulation was discontinued and the leads were explanted. Clinically significant improvements in pain (62% average reduction in Brief Pain Inventory Question #5, average pain), and functional outcomes (73% reduction in disability, Oswestry Disability Index; 83% reduction in pain interference, Brief Pain Inventory) were demonstrated. Both subjects reduced analgesic use by 83% on average, and the one subject taking opioids, stopped their usage altogether (Kapural, 2017).

The Sprint®PNS system stimulator: is a peripheral nerve stimulator indicated for up to 60 days for relief of chronic intractable, post-operative and post-traumatic pain. It is not intended for use on the cranial and facial nerve areas (SPR Therapeutics, 2022).

A study of 675 patient records of those previously implanted, derived from 4091 (6.1 reports per patient from baseline to 60 day treatment) was analyzed regarding the pain reducing effectiveness using the Sprint®PNS system stimulator. Naidu and colleagues (2021) focused on mean pain reduction percentages over a 60 day timeline to provide a more comprehensive evaluation of responses over time, and to better identify true responders and non-responders to neurostimulation pain reductive therapies as well as control for false negative and false positive responses. Four groups were analyzed as the early and delayed responders; and the early and delayed non-responders. The results demonstrated mean percent pain relief within the last two weeks of the study for the Early responder group (29.6%) who experienced a +2.4% improvement. The Delayed responder

group (29.6%) had a +49.8% mean pain reduction. The Early non-responders (33.8%) had a +5.5% pain reduction improvement. The Delayed non-responders (6.9%) experienced a -48.8% mean pain reduction within the last two weeks. Greater than 50% of the patients analyzed had pain relief with the exception of the Delayed non-responder group (Naidu, 2021).

A comparative study was performed on 75 patients with failed back surgery syndrome (FBSS) who responded to treatment with either spinal cord stimulators + peripheral nerve stimulation or spinal cord stimulators alone following a multicenter randomized clinical trial protocol. Those involved completed the 12-month follow-up: 21 in the spinal cord stimulators-only group, and 54 in the spinal cord stimulators + peripheral nerve stimulation group. Outcome measurements were of pain (visual analog scale), quality of life (36-Item Short Form Survey [SF-36]), anxiety and depression (Hospital Anxiety and Depression Scale [HADS]), overall health (EuroQol Five-Dimension [EQ-5D]), disability (Oswestry Disability Index [ODI]), and pain assessed by the McGill questionnaire. Both groups showed a significant reduction in back and leg pain at 12 months compared with baseline measurements. No significant differences were found between the groups in effect on both primary (pain) and secondary parameters (SF-36, HADS, EQ-5D, ODI, and McGill pain). In a patient subgroup with chronic back and leg pain, spinal cord stimulators alone provided similar long-term pain relief and quality-of-life improvement as the combination of peripheral nerve stimulation added to spinal cord stimulators. In patients with refractory low back pain who was not responding to spinal cord stimulators alone, adding peripheral nerve stimulation was effective in reducing pain and to be recommended. (van Heteren, 2022).

Neuromodulation provides an opportunity to reduce or eliminate the use of opioids to treat chronic low back and leg pain, but the cost and invasiveness of existing methods have limited its broad adoption, especially earlier in the treatment continuum (Kapural, 2017). Although shown to be an effective treatment option; there have been relatively few high level studies that support the unequivocal use and current amount of spinal cord stimulators for chronic nerve pain. Higher frequency of 10 kHz spinal cord stimulators have been shown to be more effective when low-frequency spinal cord stimulators have failed (Sayed, 2020).

Significant limitations remain in the evidenced based published literature over the last 10 years, that is lacking in long term data beyond 24 months, as well as adverse events (lead migration, infection, lead breakage), and device explantation rates (Malinowski, 2020).

Recommendations to close gaps include conducting additional clinical research that establishes how interventions work in conjunction with other approaches in the process of caring for patients with chronic pain, especially early in the process, when combined with goal-directed rehabilitation and appropriate medications, but recognizes that peripheral nerve stimulators have gained popularity and effectiveness with the recognition of peripheral nerve entrapments, increased use of ultrasound, and improvement in technology (The Pain Management Best Practices Inter-Agency Task Force Report, 2019).

References

On March 9, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were *MeSH: "Peripheral nerve stimulator", "fibromyalgia", "CRPS", "reflex sympathetic dystrophy", "chronic pain", "radiculopathy", "neuropathic pain"* We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

4/2022: initial review date and clinical policy effective date: 5/2022

Appendix A The Dermatomal Map of the human body that graphically represents the bands of sensory nerve innervation to the skin of the cranial and spinal nerves (UpToDate, 2022).