Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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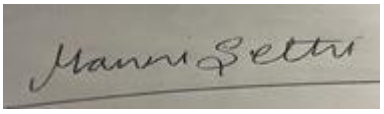
Plan: Keystone First	**Submission Date**: 5/1/2024
Policy Number: ccp.1512	**Effective Date:** 5/2022 **Revision Date:** April 1, 2024
Policy Name: Peripheral nerve stimulators for chronic nerve pain	
Type of Submission – Check all that apply: **New Policy** **Revised Policy*** **Annual Review – No Revisions** **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** See tracked changes below.	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Peripheral nerve stimulators for chronic nerve pain

Clinical Policy ID: CCP.1512

Recent review date: 4/2024

Next review date: 8/2025

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

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

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

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Standard of care treatment, including, but not limited to:

- Physical medicine and rehabilitation.
- Transcutaneous electric nerve stimulation.
- Non-opioid medications (e.g., prescribed non-steroidal anti-inflammatory drugs, acetaminophen, steroids, antidepressants, anticonvulsants, and topical medications).
- Joint injections.
- Peripheral nerve blocks.
- Trigger point injections.
- Epidural steroid injections.
- Radiofrequency ablation.
- Sympathetic nerve blocks.

- Spinal cord stimulation.
- Behavioral therapy.

Background

According to the Centers for Disease Control and Prevention, in adult populations, the prevalence of chronic pain and high impact chronic pain, defined as pain that limits work or life activities, in the past three months was 20.4% and 7.4%, respectively. Chronic pain and chronic high-impact pain occurs more often in women than men, in aged 65 and older, and in non-Hispanic whites (Zelaya, 2020).

There are many definitions to what constitutes chronic pain but, in general, it is pain that persists longer than three to six months and beyond the usual recovery time period; it may be constant or intermittent in nature. The original causes may be illness or injury or sometimes idiopathic. It is affected by environmental and psychological factors (Trent, 2023).

Managing chronic non-malignant pain remains a clinical challenge. The increasing use of opioids for pain relief and subsequent risk of opioid dependency, misuse, overdoses and deaths has led to the increased interest in non-opioid alternatives. Neuromodulation in pain medicine is a non-pharmacologic option that applies an electrical stimulus to a specific nerve to alter pain signals and reduce the perception of pain. Neuromodulators encompass an array of non-invasive, minimally invasive, and surgical options that target the spinal cord or peripheral nerves (Trent, 2023).

Peripheral nerve stimulation involves imaging-guided percutaneous surgical placement of a wire-like electrode next to a target peripheral nerve and a generator to deliver rapid electrical pulses. The patient controls the stimulation parameters as needed. The technical characteristics of peripheral nerve stimulators are similar to those of vagus, phrenic, and sacral nerve stimulators used for other conditions. Peripheral nerve field stimulation is a similar treatment in which the electrodes are placed subcutaneously in the region of the pain to stimulate fields of multiple smaller peripheral nerves (Trent, 2023).

Peripheral nerve simulators may provide lasting pain relief without the potential risks associated with pain medications. They may be a preferred option over peripheral local anesthetic nerve blocks to avoid their undesirable motor weakness effects and in patients for whom spinal cord stimulators are contraindicated. Potential indications for peripheral nerve stimulation include conditions that have neuropathic pain transmission located along a dermatomal distribution of a nerve (Trent, 2023).

The U.S. Food and Drug Administration has approved several peripheral nerve stimulators for commercial distribution, each with specific pain indications that may include chronic intractable pain. Available peripheral nerve stimulators may be implanted for either temporary 30- or 60-day use or permanent use (U.S. Food and Drug Administration, 2024).

Findings

The American Society of Pain and Neuroscience issued consensus statements for use of implantable peripheral nerve stimulation based on a systematic review of 20 randomized controlled trials and 33 prospective, observational studies. In general, limited evidence suggests peripheral nerve stimulation may offer a less invasive option for achieving mild to moderate pain relief. The recommendations apply to patients 18 years or older with chronic pain of greater than six months duration and failure of prior conservative therapy (physical therapy, pharmacologic treatment, or injection therapy). The Society found insufficient evidence supporting

stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain, but found sufficient evidence supporting peripheral nerve stimulation for the following indications (Strand, 2022):

- Supported by at least one well-designed randomized controlled trial:
    - Occipital nerve stimulation for chronic migraine headache (Grade B recommendation based on at least moderate evidence of effectiveness and benefits exceed harms).
    - Chronic hemiplegic shoulder pain (Grade B).
    - Failed back surgery syndrome using subcutaneous peripheral field stimulation as an adjunct to optimal medication management (Grade B).
    - Lower extremity neuropathic pain (Grade B).
    - Lower extremity post-amputation pain (Grade B).
- Supported by cohort or case studies and well-designed controls, preferable multicenter:
    - Mononeuropathies of the upper extremity following a positive diagnostic ultrasound-guided nerve block of the targeted nerve (Grade B).
    - Axial, mechanical low back pain (Grade B).
- Supported by experience-based opinions, descriptive studies, clinical observations, or expert committee reports:
    - Neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia (Grade C neither recommendable nor inadvisable with at least moderate evidence of effectiveness, but benefits and harms are similar and a general recommendation cannot be justified).
    - For complex regional pain syndrome type I/II or peripheral causalgia (Grade C).

A U.S. Pain Management Best Practices Inter-Agency Task Force addressed acute and chronic pain care in light of the ongoing opioid crisis. They recommended additional clinical research to establish how interventions work in conjunction with other approaches in caring for patients with chronic pain, especially early in the process, when combined with goal-directed rehabilitation and appropriate medications. They recognize the increased popularity and effectiveness of peripheral nerve stimulators with the recognition of peripheral nerve entrapments, increased use of ultrasound, and improvement in technology, but issued no specific recommendations for use (The Pain Management Best Practices Inter-Agency Task Force Report, 2019).

There is insufficient evidence to support the use of peripheral nerve stimulation for the treatment of chronic pain. The published evidence consist of retrospective reviews, case reports, small case series, and a limited number of small, randomized controlled trials of variable quality. Meta-analysis was not possible due to wide variations in study design and heterogeneous study populations. Peripheral nerve stimulation appears to be safe with few serious adverse effects. The scarring, concomitant nerve damage, migration, infection, and pain found with earlier systems has been reduced with current technology. The main reason for explantation appears to be lack of efficacy, but this has not been systematically documented.

Systematic reviews of randomized controlled trials provide conflicting conclusions regarding the efficacy of peripheral nerve stimulation or peripheral nerve field stimulation for certain chronic pain syndromes, even when using the same quality appraisal framework on the same trials. Studies generally show favorable pain reduction using objective pain scales in the short-term, but long-term data and data on functional improvement are lacking. Prospective, comparative, and well-powered studies are needed to identify the best candidates for treatment.

A systematic review evaluated 14 randomized controlled trials appraised as moderate quality (two trials) and high quality (12 trials) based on study design and clinically meaningful outcomes. Using the Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment scoring tool developed by the American Society of Interventional Pain Physicians, the investigators found (Deer, 2020):

- Level I evidence for occipital nerve stimulation for migraine headache (five trials).

- Level I evidence for chronic low back pain (targeting the cluneal nerve and its branches) (three trials).
- Level II evidence for sphenopalatine ganglion stimulation for the treatment of cluster headache (one trial).
- Level II evidence for poststroke shoulder pain (targeting the axillary and suprascapular nerves) (one trial).
- Level II evidence for neuropathic pain of the extremities and trunk (one trial).
- Level III evidence for chronic pelvic pain (three trials).

The Agency for Healthcare Research and Quality conducted a comparative effectiveness review of interventional treatments for acute and chronic pain for which important uncertainty or controversy regarding use exists. There was insufficient evidence to assess peripheral nerve stimulation for upper extremity (ulnar, median, and radial) peripheral neuropathic pain (Chou, 2021). The Agency review included one fair quality randomized control trial (n = 94) that enrolled 26 participants with upper extremity pain. Compared to sham, peripheral nerve stimulation was associated with greater percent change from baseline in pain intensity at three months, but the estimate was imprecise and not statistically significant (mean difference -19.8%, 95% confidence interval -44.6 to 5.0) (Deer, 2016).

Another systematic review identified one randomized controlled trial for each of the chronic pain conditions below, using the Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment scoring tool for quality assessment (Helm, 2021).

- Cluster headache (moderate quality).
- Chronic pelvic pain (moderate quality).
- Hemiplegic shoulder pain after stroke (moderate quality).
- Neuropathic extremity or truncal nerve pain (moderate quality).
- Post-amputation pain (high quality).

Using the Cochrane review methodologic quality assessment and the Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment tool, a systematic review found Level I and II evidence supporting peripheral nerve stimulation in chronic migraine headache; Level II evidence in cluster headache, post-amputation pain, chronic pelvic pain, chronic low back and lower extremity pain; and Level IV evidence in peripheral neuropathic pain and postsurgical pain. Peripheral field stimulation has Level II evidence in chronic low back pain, and Level IV evidence in cranial pain (Xu, 2021).

A systematic review analyzed three randomized controlled trials and 11 observational studies of peripheral nerve stimulation for upper or lower extremity neuropathic pain. Using the Grading of Recommendations Assessment, Development and Evaluation criteria, very low quality or low quality evidence supported modest to substantial improvement in pain and neurological function after implantation. The highest level of evidence was for post-amputation pain. The authors call for prospective and well-powered studies to assess these results (Char, 2022).

For treating post-amputation pain, one systematic review identified three randomized control trials and 10 observational studies, all of low quality according to Grading of Recommendations, Assessment, Development, and Evaluations criteria. The results suggest peripheral nerve stimulation may produce clinically significant pain improvements (Smith, 2023).

Systematic reviews of observational research have identified emerging potential uses for peripheral neuromodulation. These indications are chemotherapy-induced peripheral neuropathy (D'Souza, 2022a), diabetic neuropathy (D'Souza, 2022b), suprascapular nerve entrapment (Vij, 2022), post-herpetic neuralgia (Lin, 2019), and trigeminal pain (Ni, 2021; Sarica, 2022). The generally positive results require confirmation in prospective, randomized studies.

In 2024, we added two systematic reviews and one guideline from the American Society of Pain and Neuroscience on treatments for low back pain (Strand, 2022). No policy changes are warranted.

A systematic review of nine low-quality studies suggests peripheral nerve stimulation may be effective for alleviating chronic knee pain following total knee arthroplasty. The results should be confirmed in higher quality studies (Amirianfar, 2023).

For chronic low back pain, a systematic review of six randomized controlled trials and 23 mixed observational designs and case reports analyzed peripheral nerve stimulation modalities as primary therapy (n = 828) and salvage therapy after spinal cord stimulator placement (n = 173). The modalities were stimulator placement at the medial branch nerves, peripheral nerve field stimulation, and neuromuscular lead placement in the multifidus muscle. All studies consistently reported positive improvement with peripheral nerve stimulation from baseline, but the clinical significance of modest improvements was unclear. The overall quality of the evidence was graded very low to low, limited by heterogeneous treatment, outcome measures, statistical analyses, and inconsistent results. In some comparative studies, there was no difference in treatment effects between the intervention and control cohorts, suggesting a potential placebo effect. Longer term follow-up data with a comparator is needed to determine the net health outcome of peripheral nerve stimulation (D'Souza, 2023).

References

On January 26, 2024, 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 "Peripheral nerve stim*," "fibromyalgia," "CRPS," "reflex sympathetic dystrophy," "chronic pain," "radiculopathy," and "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

4/2023: Policy references updated.

4/2024: Policy references updated.