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Medical Policy

Subject:	**Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain**		
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Description/Scope

This document addresses implantable peripheral nerve stimulation devices as a treatment for pain. These devices are temporarily or permanently implanted and provide direct electrical stimulation to peripheral nerves.

Note: For information on similar technologies used to treat pain, please see the following related documents:

- **CG-DME-04 Electrical Nerve Stimulation, Transcutaneous, Percutaneous**
- **DME.00011 Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices**
- **SURG.00112 Implantation of Occipital, Supraorbital or Trigeminal Nerve Stimulation Devices (and Related Procedures)**

Position Statement

Investigational and Not Medically Necessary:

Implantable peripheral nerve stimulation devices are considered investigational and not medically necessary for all indications including, but not limited to, treatment of acute and chronic pain.

Rationale

SPRINT® Peripheral Nerve Stimulation (PNS) System

A randomized controlled trial (RCT) was published by Gilmore and colleagues in 2019 on percutaneous peripheral nerve stimulation with the SPRINT device for treatment of chronic neuropathic post-amputation pain. The study included 28 lower-extremities amputees who were randomized to 4 weeks of percutaneous

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stimulation or sham treatment. After this 4-week period, the sham group could cross over to receive active treatment for 4 weeks and the active treatment group received an additional 4 weeks of treatment. The proportion of participants with at least a 50% pain reduction at 4 weeks, the primary outcome measure, was significantly higher in the active treatment group (7 of12, 58%) than the sham group (2 of 14, 14%), p=0.037. At week 8, 8 of 12 (67%) individuals assigned to active treatment reported at least a 50% reduction in pain. After crossing over to active treatment after 4 weeks, the proportion of individuals assigned to the sham group that reported at least a 50% reduction in pain remained the same at 14%. The study had a small sample size and a short duration of comparative follow-up.

StimRouter® PNS System

An RCT evaluating the StimRouter device was published by Deer and colleagues in 2016. Eligibility criteria included age at least 22 years, severe intractable pain of peripheral nerve origin for at least 3 months and worse pain level in the last 24 hours rated as at least 5 on a 10-point numerical rating scale (NRS). Following implantation of the device and a 14-24 day healing period, 94 individuals were randomized to receive active treatment (n=45) or to a no-stimulation control group (n=49) for 3 months. The study is described as being "double-blind"; however, no information regarding the blinding process is included in the study, nor is it clear whether the blinding protocol was adequate or appropriately conducted. Both groups were able to continue receiving stable doses of medications. The primary efficacy outcome was pain measured by the 10-point NRS. Responders were defined as individuals with at least a 30% decrease in the NRS with no upward titration in the pain medicine regimen. At 3 months, mean average pain decreased by 27.2% in the treatment group and 2.3% in the control group, p<0.0001. The NRS scores were not reported at 3 months. A total of 17 of 45 individuals in the treatment group (38%) and 5 of 49 in the control group (10%) were considered to be responders, p=0.0048.

After the 3 month treatment period, individuals in the control group were offered the option of crossing over to active treatment; only 30 of 45 (67%) consented. Three months after crossing over to the treatment group, 9 of 30 individuals (30%) were categorized as responders. Data were not available on the 15 individuals in the control group who did not cross over to active treatment. Study participants were followed for safety outcomes for a mean of 320 days. There were a total of 51 reported device-related adverse events (AEs), none of which were considered serious adverse events (SAEs). The AEs were mainly localized to the site of surgery or stimulation area. A commonly reported AE was skin irritation (13 individuals); 2 participants with prolonged skin sensitivity in the area of the electrode patch discontinued the study. Seven participants underwent explantation of the device, 5 due to insufficient pain relief, 1 due to chronic sensitivity to the electrode patch and 1 due to lead rejection.

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Although statistically significantly more participants were considered to be responders at 3 months in the active treatment group, a majority of individuals in the treatment group did not respond (using the definition of at least a 30% decrease in the NRS with no upward titration in pain medication). It is unclear whether the primary outcome is clinically meaningful, and no rationale is provided to explain why a 30% decrease in pain score was chosen given that a 50% reduction in pain is considered standard of care to determine whether someone is a "responder" to similar devices (that is: spinal cord stimulation). A substantial number of AEs were also reported in the study. Other study limitations include a relatively short follow-up period (3 months of comparative follow-up), and a high dropout rate; over half of the implanted participants lacked 12 month safety data.

There are also several case series evaluating the StimRouter device. Oswald and colleagues (2019) published a study with 39 individuals who received a StimRouter device for chronic neuropathic pain. Individuals were surveyed by the device manufacturer before and 3 to 6 months after the device was implanted. Respondents were asked to assess their pain using a 10 point visual analogue scale (VAS) and, in the post-test, to estimate their percent improvement in activity. No standardized instrument was used to assess activity level. The mean VAS score was 9.8 before implantation and 2.4 after implantation (no p-value provided). At follow-up, the reported mean improvement in activity level was 72%. There was no placebo or comparison group in this study.

Previously, in 2010, a small feasibility study evaluating the feasibility and safety of the StimRouter device was published by Deer and colleagues. The study included 8 adults at least 18 years old with carpal tunnel syndrome and chronic pain for at least 3 months despite oral medication use. All 8 individuals underwent successful device implantation with successful programming of the devices on the first attempt. There were 3 reported AEs, only 1 of which, an allergic reaction to the antiseptic, was considered to be procedure-related. No SAEs were reported. During a 5-day stimulation period, mean average pain scores decreased from 6.7 (out of 10) to 6.2 Mean pain "right now" was 6.4 at baseline and 6.8 at follow-up. P-values were not reported.

StimQ PNS System
No published studies evaluating the StimQ device were identified.

Summary
Overall, there is a lack of literature evaluating long-term efficacy and adverse events associated with implantable PNS devices. Long-term data are especially important for these technologies due to the invasive

(and in some cases, permanent) nature of theses device. Potential long-term complications include those seen with spinal cord stimulators, including lead migration, lead fracture, seroma, infection and hematoma. Moreover, long-term efficacy is not known, including the extent to which individuals develop tolerance to the stimulation over time (as has been seen with spinal cord stimulators).

Background/Overview

Pain is one of the most common reasons that adults seeks medical care. Estimates of the prevalence of chronic pain among U.S. adults range from about 10-40% and can restrict mobility, the ability to work, and daily activities. A national population-based survey, conducted in 2016, found that 20.4% of U.S. adjust had chronic pain and 8% had chronic pain with high impacts on their lives (Dahlhamer, 2018). Treatments for chronic pain include exercise, physical therapy and topical, oral and injectable medications. A variety of electrical stimulation devices are available to treat pain. Many of these are surface or percutaneous devices, but some are temporarily and permanently implanted. Implanted devices have potential safety issues such as adverse effects associated with the implantation process, device-related pain and lead migration.

A temporarily implanted device, the SPRINT peripheral nerve stimulation system (SPR Therapeutics, Cleveland, OH), was cleared by the FDA (K181422) in 2018. The device is implanted for up to 60 days. FDA documents state that the system consists of a percutaneous electrode placed using an introducer needle near a target peripheral nerve and an external pulse generator that delivers stimulation to the percutaneous electrode. The FDA further states that the device is indicated for treatment of post-traumatic pain, post-operative pain and chronic, intractable pain.

Other FDA-cleared devices are permanently implanted. The StimQ Peripheral Nerve Stimulator (PNS) System (StimQ LLC, Fort Lauderdale, FL) was cleared by the FDA (K152178) in March, 2016 for "pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach". The FDA document notes that the StimQ system is not intended to treat pain in the craniofacial region. The StimQ system includes an implantable stimulator and a transmitter that is worn externally. Before having a device implanted, potential users undergo a trial period with the trial lead to see whether their pain is successfully relieved.

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Another permanently implanted device, the StimRouter Neuromodulation System (Bioness Inc., Valencia, CA), was cleared by the FDA (K190047) in October 2019 for "pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications)." The device is not intended to treat craniofacial pain. The StimRouter system consists of an implantable lead and external accessories, which includes a programmer and an external pulse transmitter.

Definitions

Peripheral nerves: The portion of the nervous system other than the central nervous system (brain and spinal cord).

Visual analog scale (VAS): A pain assessment tool that helps an individual describe the intensity of their pain by marking on a line their level of discomfort; a VAS is a straight line with the left end of the line representing no pain and the right end of the line representing the worst pain.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes when specified as an implanted peripheral nerve stimulation device; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

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HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Deer TR, Levy RM, Rosenfeld EL. Prospective clinical study of a new implantable peripheral nerve stimulation device to treat chronic pain. Clin J Pain. 2010 Jun; 26(5):359-372.
2. Deer T, Pope J, Benyamin R et al. Prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. Neuromodulation. 2016; 19(1):91-100.
3. Gilmore C, Ilfeld B, Rosenow J, et al. Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial. Reg Anesth Pain Med. 2019; 44(6):637-645.
4. Oswald J, Shahi V, Chakravarthy KV. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. Pain Manag. 2019; 9(6):551-558.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001-1006.
2. Food and Drug Administration. K152178: StimQ Peripheral Nerve Stimulator (PNS) System. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152178.pdf. Accessed on October 1, 2020.

3. **Food and Drug Administration. K181422: SPRINT Peripheral Nerve Stimulation System. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf. Accessed on October 1, 2020.**
4. **Food and Drug Administration. K190047: StimRouter Neuromodulation System. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K190047. Accessed on October 1, 2020.**

Websites for Additional Information

1. **American Society of Retional Anesthesia and Pain Management. Treatment options for chronic pain. Available at: https://www.asra.com/page/46/treatment-options-for-chronic-pain. Accessed on October 5, 2020.**

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Peripheral nerve stimulation
SPRINT® PNS System
StimRouter® PNS System
StimQ PNS System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.