

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

Reactiv8 Implantable Restorative Neurostimulation

The Reactiv8 device was initially evaluated in an uncontrolled study, Reactiv8-A, which included 53 individuals with chronic (at least 90 days) low-back pain who had not obtained satisfactory pain relief with physical therapy or medication and were not eligible for spinal surgery or spinal cord stimulation (SCS). All individuals were implanted with the Reactiv8 neurostimulation device. As reported by Deckers and colleagues (2018), 58% of participants were considered responders at 90 days, defined as at least a 2-point reduction in mean pain score from baseline on a 10-point numerical scale and who did not have a clinically meaningful increase in pain medication. For the 90-day assessment, participants were asked to report single-day pain on the day of evaluation and the responder rate at 90 days was 58%. At 1 year, 57% of participants reported at least a 2-point reduction in single day pain. Longer-term outcomes were reported by Mitchell and colleagues in 2021. Follow-up data were available for 39 participants at 2 years, 37 participants at 3 years and 34 participants at 4 years. Among participants who completed 4 years of follow-up, the mean change in the numerical pain score was 2.6 points at 1 year, 2.8 points at 2 years, 3.2 points at 3 years and 3.5 points at 4 years. The authors did not report responder rates after the 90-day assessment of the primary outcome.

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In 2021, Gilligan and colleagues published results of a randomized controlled trial (RCT), Reactiv8-B, which was double-blind and sham-controlled (low-level stimulation) (Gilligan, 2021). The RCT included 204 individuals, 102 per group. Eligibility criteria included age 22 to 75 years old, a diagnosis of non-neuropathic mechanical chronic low-back pain, a history of pain on at least half of the days in the previous year despite at least 90 days of medical management and at least one attempt at physical therapy treatment, pain level between 6.0 and 9.0 on a 10-cm visual analogue scale (VAS) over a 7-day period, an Oswestry Disability Index (ODI) between 21 and 60 points (on a 100-point scale) and a positive prone instability test. Individuals were excluded if they had prior lumbar spine surgery below T8 or prior spinal fusion at any level, or identified pathology, scoliosis or sacroiliac joint pain as the likely cause of chronic low-back pain.

The primary study outcome, which was done using an intention to treat (ITT) analysis, was the proportion of participants who responded to treatment at 120 days. Response was defined as at least a 30% reduction from baseline in 7-day recall of average low-back pain, measured by the VAS, without an increase in pain medication from baseline. The proportion of responders at 120 days was 57.1% in the active treatment group and 46.6% in the sham group. The primary outcome, response rate at 120 days, did not differ significantly between groups (difference of 10.4%, 95% confidence interval [CI], -3.3% to 24.1%; $p=0.138$).

In terms of individual components of the primary endpoint, mean VAS decreased by 3.3 points in the active treatment group and by 2.4 points in the sham group ($p=0.032$), and 9 participants in each group increased pain medication; for 6 individuals in the active treatment group, pain medication increase was unrelated to low-back pain. In a secondary analysis of the primary endpoint, a cumulative-proportion-of-responders analysis of primary outcome data across all possible response thresholds found a statistically significant difference between groups ($p=0.0499$), favoring the treatment group; the p -value was barely below the $p=0.05$ significance threshold. After 120 days, the study was unblinded and participants in the sham group were offered active treatment; all sham group participants chose to receive active treatment. Serious device- or procedure-related adverse events were reported in 8 individuals (4%) before the 120-day follow-up. Among the 176 individuals who completed the 1-year follow-up, 130 (74%) had 30% or greater improvement in low-back pain compared with baseline, with a mean average reduction in VAS of 4.3 points (standard deviation [SD], 2.6 cm). There was no comparative analysis at the 1-year follow-up.

Gilligan and colleagues have reported 2-year (2023a), 3-year (2023b), and 5-year (2024) follow-up data on individuals who received active treatment. No sham comparison was done in this analysis since all sham participants had ultimately chosen to receive the intervention. The initial group in these follow-up analyses was the 204 individuals in the Reactiv8-B who had either originally received the implanted device or had received it after unblinding at 120 days. At baseline, the mean VAS was 7.3 cm (SD, 0.7 cm), the mean ODI was 39 (SD, 10) and the mean EQ-5D-5L index (measuring quality of life) was 0.585 (SD, 0.174). Data were available for 190 participants at 6 months, 176 (86%) at 1 year, 156 (79%) at 2 years, 133 (65%) at 3 years and 126 (62%) at 5 years. The authors reported both a completer analysis and an ITT analysis using imputed data. Among the 156 individuals who completed the 2-year follow-up, the mean VAS had decreased by a mean of 4.8 (SD, 2.0) points (95% CI, -5.2 to -4.5; $p<0.0001$), and 72% of participants had at least a 50% reduction in VAS. The mean ODI score decreased by 21.4 (SD, 1.3) points (95% CI, -24.0 to -18.7; $p<0.0001$) and 62% of participants had a ≥ 20 -point ODI reduction. The mean EQ-5D-5L index (measuring quality of life) improved by 0.218 ± 0.017 points (95% CI, 0.184 to 0.253; $p<0.0001$). Among the 133 individuals who completed the 3-year follow-up, 77% had at least a 50%

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reduction in VAS and 63% had ≥ 20 -point ODI reduction, with an average reduction of 32 points. The mean EQ-5D-5L index improved by 0.220 ± 0.017 points (95% CI, 0.186 to 0.253, $p < 0.0001$). In the imputed ITT analyses, there remained statistically significant improvement in reported outcomes compared with baseline. Among the 126 completers at 5 years, mean VAS was 2.4 points (SD, 2.0) and 89 individuals (71.8%) had $\geq 50\%$ improvement in VAS compared with baseline. ODI decreased by a mean of 22.7 (SD, 1.4) points compared with baseline and 77 individuals (61.1%) had ≥ 20 -point ODI reduction. In addition, the mean EQ-5D-5L index improved by 0.231 (SD 0.018) points compared with baseline (95% CI, 0.195–0.267; $p < 0.0001$). At 5 years, the proportion of study completers with a reduction in VAS of $\geq 50\%$ and/or a reduction in ODI of ≥ 20 points, without an increase in either, was 78.2%. The authors did not report the original primary study outcome, discussed above, which defined treatment response as at least a 30% reduction from baseline in 7-day recall of average low-back pain, measured by the VAS, without an increase in pain medication from baseline.

Fewer than 80% of participants contributed data to the 2-year analysis and 62% were included by the 5-year analysis. Statistical imputation may not accurately reflect the experience of the missing participants (no sensitivity analysis was reported). Moreover, in the 90 days leading to the 24-month follow-up, device use was 42%, which makes it more difficult to attribute changes in pain and function outcomes to use of the device. Device use was not reported in the 3-year follow-up study. In terms of safety, no additional device- or procedure-related SAEs were reported after the first year of follow-up. The number of permanent system removals were 17 of 204 (8.3%) in the first 12 months, 14 (6.9%) between 12 and 24 months, 14 (6.9%) between 24 and 36 months, 7 (3.4%) between 36 and 48 months and 10 (4.9%) between 48 and 60 months. The most common reason for permanent system removal was inadequate response (a total of 27/204, 13%).

A protocol for an RCT comparing Reactiv8 with optimal medical management (NCT04803214) was published by Gilligan and colleagues in 2023. In this study, individuals will be followed for one year prior to crossover. Data on the primary endpoint, the difference between groups in mean change in the ODI at one year, is expected in 2024.

The Food and Drug Administration (FDA) premarket approval (PMA) document (2020) noted, “the study failed the prespecified primary effectiveness endpoint analysis”. It further stated:

The primary endpoint was a comparison of patients in the active and control groups who achieved a 30% reduction in pain from baseline with no increase in pain medications or muscle relaxants. A 30% reduction in pain was selected to ensure that a successful active treatment would be clinically relevant to the patient. However, using this dichotomous endpoint, the result was not statistically significant as compared to the control. This may have been due to a number of factors including the use of an active control which would be likely to provide some benefit to the subjects in the Control group as well as increase the potential effect of placebo. Importantly, however, the cumulative response analysis did achieve a p -value < 0.05 . In addition, the patients’ percent pain relief and disability as measured by the ODI supported the clinical benefit of the active treatment over the control.

Results of an uncontrolled post-market study were reported by Thomson and colleagues in 2021. A total of 42 individuals who were implanted with a restorative neurostimulation device were included in the study and data on 27 individuals were available 2 years after device activation. Mean numerical pain scores were 7.0 (standard error [SE], 0.2) at baseline and this decreased to a mean of 3.5 (SE, 0.3) at 2 years, $p < 0.001$. Moreover the mean ODI

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score decreased from 46.6 (SE, 2.2) at baseline to a mean of 29.2 (SE, 3.1) at 2 years, $p < 0.001$. This study did not have a comparison group.

Ardeschiri and colleagues (2022) reported findings of an uncontrolled study of the Reactiv8 device in individuals recruited from the community from a single surgeon. The study included 44 consecutively recruited individuals with chronic mechanical pain associated with minimal leg pain that was refractory to conservative treatment. Participants were implanted with the Reactiv8 device, devices were programmed 14 days later, with stimulation parameters adjusted later as needed. Individuals were instructed to have two 30-minute stimulation sessions per day while at rest in a supine or lateral position. The authors did not specify primary efficacy outcomes of interest. Mean baseline scores were 7.7 (SE, 0.2) on the numerical rating score (NRS), 43.0 (SE, 2.8) on the ODI and 0.504 (SE, 0.034) on the EQ-5D-5L. Scores on each of the three efficacy measures increased significantly from baseline to the 12-month follow-up, using both a completer analysis of 40 individuals and ITT analysis in all 44 participants. In a completer analysis, after 12 months, 68% of individuals had moderate ($\geq 30\%$) reductions in pain, 52% had substantial ($\geq 50\%$) reductions in pain and 48% had a NRS < 3 which was considered to signify mild pain or being pain-free. In terms of safety, there were no lead migrations but there was one revision for a lead fracture. In addition, one participant had isolated sacroiliac joint pain that resolved after treatment and two participants chose to have the device removed due to lack of efficacy. Limitations of the study include lack of a comparison group and lack of information on participants' compliance with stimulation session recommendations.

SPRINT® Peripheral Nerve Stimulation (PNS) System

An 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 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 of 12, 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.

In 2022, Huntoon and colleagues published a retrospective review of 6,160 individuals who received a 60-day course of treatment with the Sprint device and were included in a manufacturer database. At baseline, individuals had a mean baseline average pain score of 6.6 (SD, 1.7) and mean baseline worst pain score of 9.0 (SD, 1.2). At the end of the course of treatment, 71% (4,348/6,160) of individuals met the primary endpoint criteria, at least 50% pain relief and/or an improvement in quality of life. Quality of life improvement was defined as meeting criteria for at least minimal clinical improvement on the Patient Global Impression of Change (PGIC). This study had a large sample size, but was retrospective, short-term and lacked a comparison group.

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 NRS. Following implantation of the device and a 14-24

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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.

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 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.

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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 and Nalu Neurostimulation System

StimQ PNS and the Nalu Neurostimulation systems each received 510(k) clearance from the FDA based on “substantial equivalence” to predicate devices. To get 510(k) clearance, the manufacturers were not required to conduct controlled trials demonstrating the efficacy of the technologies for the cleared indications.

No published studies evaluating the StimQ PNS System were identified.

Hatheway and colleagues (2024a) reported on an RCT evaluating use of the Nalu system known as the COMFORT study. Blinding of study participants or outcome assessment was not mentioned. To be eligible, individuals needed to be diagnosed with postsurgical/post-traumatic peripheral neuralgia, pain due to postsurgical scar formation, nerve entrapment or mononeuropathy, or osteoarthritic pain affecting the lower back, shoulder, knee, foot or ankle. Individuals with complex regional pain syndrome, peripheral neuralgia of metabolic origin or postherpetic origin, and individuals taking at least 90 morphine mg equivalents per 24 hours were excluded. Participants were randomized to an active arm (Nalu system plus conventional medical management [CMM]) or a control arm (CMM only). Individuals in the active arm first underwent a temporary trial procedure. Those with at least a 50% reduction in pain during the trial period were considered responders and received a permanent implant. Those with less than a 50% reduction in pain during the trial period were considered trial failures and exited the study. After 3 months, individuals in the control group were able to cross over to the active group; thus, the randomized comparison was only for 3 months.

A total of 89 individuals were randomized, 58 to the active arm and 31 individuals to the control arm. In the active arm, 1 person withdrew before the temporary trial and 57 underwent temporary implantation. One individual failed the temporary trial and 8 individuals in the active group withdrew from the study after temporary implantation, leaving 48 individuals in the active treatment group, 46 of whom were included in a modified intention to treat (mITT) analysis. In contrast, all 31 control arm participants were included in the mITT. The 3-month analysis included 43 active arm participants and 29 control arm participants; 2 individuals in the active arm and 3 in the control arm missed the 3-month follow-up visit and were excluded from the primary analysis.

The primary efficacy measure was the percentage of responders in each group at 3 months, prior to crossover. Responder was defined as at least a 50% reduction in pain relative to baseline, as measured by the numeric pain score in the Brief Pain Inventory Question 5 (BPI- Q5) for their primary area of pain. The responder rate was 84% (36 of 43) at 3 months in the active arm and 3% (1 of 29) in the control arm ($p<0.001$). The percent of pain relief at 3 months, a secondary outcome, was 67% in the active arm and 6% in the control arm ($p<0.001$). At 6 months, after crossover, the responder rate was 88% (37 of 42) in the active arm; 6-month data were not available for the control arm.

This study has a number of limitations. It lacked a sham control group, which can help identify the extent to which a response might be due to the placebo effect; sham controls are particularly important when outcomes are subjective as with pain. Similarly, the study was not said to be blinded. With a subjective outcome, individuals in the control group might have been disappointed and individuals in the active group might have expectations of

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efficacy due to receiving a novel intervention. In addition, a substantial proportion of the active arm were excluded from the study post-randomization and thus the characteristics in the two groups can no longer be assumed to be similar. Only 43 of 58 randomized individuals in the active arm, 74%, were included in the primary efficacy analysis compared with 29 of 31 (94%) in the control arm.

Hatheway and colleagues (2024b) reported 12-month findings of the COMFORT study. In the original trial, 58 individuals were randomized to the active arm and 31 to the control arm. At three months, 24 subjects in the control arm crossed over to the active arm, for a total of 82 actively treated individuals. Of these 82 individuals, 61 (74%) completed the 12-month follow-up. The responder rate for the 61 individuals at 12 months was 87%, with an average pain reduction of 69%. Mean pain scores as measured by the NRS improved from 7.5 (SD, 1.20) at baseline to 2.3 (SD, 1.7) at 12 months. There was no control or comparison group at 12 months.

Other Considerations

In 2022, the American Society of Pain and Neuroscience (ASPN) published a clinical guideline on implantable PNS for treatment of chronic pain in adults who had chronic pain for at least 6 months and failed prior conservative therapy. This was a consensus guideline that incorporated a systematic review of the literature. Decisions were made by an international multidisciplinary panel. Per the ASPN protocol, although most authors had financial conflicts of interest, one of the primary authors did not have financial conflicts of interest and reviewed the paper for bias. In addition, according to the process, individuals would recuse themselves from decisions when a conflict of interest existed. The literature review included 20 RCTs and 22 prospective observational studies. The guideline publication did not discuss doing any critical appraisal of potential biases or limitations of the individual studies, nor did it state methodological criteria for determining high-quality studies such as blinding, consistency of outcome reporting, dropout rates and length of follow-up.

Key relevant recommendations are as follows:

Upper Extremities

- PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain. (B)
- PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief. (B)

Low Back/Trunk

- Subcutaneous peripheral field stimulation and optimal medication management may offer moderate improvement in pain intensity for failed back surgery compared to optimal medication management alone. (B)
- There is evidence that PNS of lumbar medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain. (B)
- There is limited evidence that PNS may alleviate pain in neuropathic pain syndrome involving the trunk and back including radiculopathy and post-herpetic neuralgia. (C)

Lower Extremities

- PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief. (B)

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- PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief. (B)

Note: Degree of recommendation:

A: Extremely recommendable (good evidence that the measure is effective and that benefits outweigh the harms)

B: Recommendable (at least moderate evidence that the measure is effective and that benefits exceed harms)

C: Neither recommendable nor inadvisable (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified)

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 these devices. 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 seek 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. adults 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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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 include a programmer and an external pulse transmitter.

The ReActiv8 Implantable Neurostimulation System (Mainstay Medical, Brooklyn Center, MN) received premarket approval from the FDA (P190021) in June 2020. The FDA approved the system for:

Bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery.

The system includes a programmable implantable pulse generator and percutaneous leads.

The Nalu Neurostimulation System (Nalu Medical, Carlsbad, California) was cleared by the FDA (K203547) in March 2021 for both spinal cord stimulation and peripheral nerve stimulation. The peripheral nerve stimulation indication is for adults with “severe intractable chronic pain of peripheral nerve origin.” The clearance notes that the Nalu system is “not intended to treat pain in the craniofacial region.” Use of the device involves up to 30 days of trial stimulation to determine efficacy prior to permanent implantation.

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)

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64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64697	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array

HCPCS

For the following HCPCS codes when specified as **components of an implantable peripheral nerve stimulation device**:

A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

ICD-10 Diagnosis

All diagnoses

When services are also Investigational and Not Medically Necessary:

HCPCS

C9807	Nerve stimulator, percutaneous, peripheral (e.g., Sprint peripheral nerve stimulation system), including electrode and all disposable system components, non-opioid medical device
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ICD-10 Diagnosis

All diagnoses

References

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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
Reviewed	11/14/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale, Background/Overview and References sections. Updated Coding section with 01/01/2025 HCPCS changes, added C9807.
	04/01/2024	Updated Coding section with 04/01/2024 HCPCS changes; added A4438.
Reviewed	11/09/2023	MPTAC review. Updated Rationale, Background/Overview and References sections. Updated Coding section with 01/01/2024 CPT changes; added 64596, 64597 and updated descriptor for 64590.
	03/29/2023	Updated Coding section with 04/01/2023 HCPCS changes, added L8678; also added L8681.
Reviewed	11/10/2022	MPTAC review. Rationale and References sections updated.
Reviewed	11/11/2021	MPTAC review. Rationale, References and Index sections updated. Updated Coding section with 01/01/2022 CPT descriptor change for 64575.
New	11/05/2020	MPTAC review. Initial document development.

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