Implantable Peripheral Nerve Stimulation Devices as a

Policy # 00473
Original Effective Date: 07/15/2015
Current Effective Date: 08/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Electrical Nerve Stimulation Devices is addressed separately in medical policy 00142.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Note: Occipital Nerve Stimulation is addressed separately in medical policy 00253.

Note: Spinal Cord and Dorsal Root Ganglion Stimulators is addressed separately in medical policy 00260.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers implantable peripheral nerve stimulation devices for all indications including, but not limited to, treatment of acute and chronic pain to be **investigational.***

Note:
Examples of implantable peripheral nerve stimulation devices (not limited to): Nalu Neurostimulation System, Peripheral nerve stimulation, ReActiv8 Implantable Neurostimulation System, SPRINT®‡ PNS System, StimQ PNS System, StimRouter®‡PNS System.

Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain

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Background/Overview

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

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.

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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 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) and 3-year follow-up data (2023b). The initial participant group in these 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. No sham comparison was possible in this analysis as all sham participants had ultimately chosen to receive the intervention. 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, and 133 (65%) at 3 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% 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. 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 only 65% were included in the 3-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 system removals were 19 of 204 (9.3%) in the first 12 months, 12 (5.8%) between 12 and 24 months and 14 (6.9%) between 24 and 36 months. For revisions, the numbers were 10 of 204 (4.9%) in the first 12 months, 5 (2.5%) between 12 and 24 months and 2 (1.0%) between 24 and 36 months.

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 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.

Ardeshiri 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 (≥30%) reductions in pain, 52% had substantial (≥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 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. 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 Systems
No published studies evaluating the StimQ PNS System or the Nalu Neurostimulation System were identified. These devices received 510(k) clearance from the FDA based on "substantial equivalence" to predicated 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.

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).

For individuals who have peripheral, neuropathic, chronic pain who receive peripheral nerve stimulation (PNS), the evidence includes 1 randomized controlled trial (RCT). Relevant outcomes are symptoms, medication use, and quality of life. The RCT reported a statistically significant difference between the treatment group and control group at 90 days in mean reduction in average pain from baseline (27.2% vs. 2.3%; $p<.0001$) and reported 38% responders, defined as having at least a 30% decrease in the numerical rating scale (NRS) with no upward titration in pain medications, in the treatment group. The RCT had a sample size of 94 with broad descriptions of pain diagnoses, including diagnoses beyond the labeled indications, and a lack of sample population diversity that is not generalizable to the US. There was 51% missing follow-up data at 12 months. Additional evidence from RCTs with larger sample sizes and longer durations of comparative data are necessary to assess the efficacy and durability of PNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information/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.

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06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. New policy.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes and CPT coding update
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Title changed from "Peripheral Subcutaneous Field Stimulation" to "Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain". Extensive policy revisions. Added a *Note* after the INV statement listing the examples of implantable nerve stimulation devices.
12/12/2023	Coding Update

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03/27/2024 Coding Update
07/02/2024 Medical Policy Committee review
07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2024 Coding update
Next Scheduled Review Date: 07/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64555, 64575, 64590, 64596, 64597, 64598
HCPCS	A4438, C1767, C1778, C1787, C1816, C1883, C1897, L8678, L8979, L8680, L8681, L8683 Add code effective 01/01/2025: C9807
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain

Policy # 00473
Original Effective Date: 07/15/2015
Current Effective Date: 08/12/2024

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.