Implanted Electrical Stimulator for Spinal Cord (for Louisiana Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Implanted electrical spinal cord stimulators are proven and medically necessary for treating the following conditions in certain circumstances, when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions:

- Complex regional pain syndrome (CRPS)
- Painful lower limb diabetic neuropathy
- Failed back surgery syndrome

Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating the following conditions due to insufficient evidence of efficacy:

- Chronic intractable back pain without prior spine surgery
- Refractory angina pectoris

Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions.

Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy.

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Spinal Cord Stimulator (SCS) Insertion.

Click here to view the InterQual® criteria.

Note: Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

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HCPCS Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
*C1816	Receiver and/or transmitter, neurostimulator (implantable)
*C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
*C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
*C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads
*C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
*C1897	Lead, neurostimulator test kit (implantable)
*L8679	Implantable neurostimulator, pulse generator, any type
*L8680	Implantable neurostimulator electrode, each
*L8682	Implantable neurostimulator radiofrequency receiver
*L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
*L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
*L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
*L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

Clinical Evidence

Painful Diabetic Neuropathy

A 2022 Hayes report on spinal cord stimulation (SCS) for relief of neuropathic pain made the following conclusions:

- For SCS for the treatment of chronic neuropathic pain associated with complex regional pain syndrome (CRPS) or diabetic neuropathy (DPN) that has not responded adequately to standard nonsurgical therapies there is a small body of low-quality evidence showing some positive benefit of SCS compared with standard alternatives.
- There is uncertainty regarding the magnitude of SCS treatment benefit.
- SCS is associated with a small to moderate risk of complications that may require reoperation to manage complications or for device removal.

In 2022, D'Souza and colleagues systematically reviewed the literature for evidence on conservative, pharmacological, and neuromodulation treatment options for painful diabetic neuropathy (PDN). The authors uncovered that intensive glycemic control with insulin for individuals with type 1 diabetes might be related to decreased odds of distal symmetric polyneuropathy compared to those who receive conventional insulin therapy. The first-line pharmacologic treatment for PDN includes gabapentinoids and duloxetine. Second-line pharmacologic modalities approved by the Food and Drug Administration (FDA) include tapentadol and an 8% capsaicin patch. The authors successfully reviewed the treatment options for PDN and noted the high level of evidence (level 1) for dorsal column SCS for treating PDN.

Xu et al. (2022) performed a systematic review to evaluate the strength of evidence on interventional management options for PDN and made evidence-based recommendations for clinical practice. After the completed search, ten randomized clinical trials, eight systematic reviews/meta-analyses, and five observational studies on interventional modalities for PDN were uncovered. Each article used pain as the primary outcome. The search revealed moderate to strong evidence supporting the utilization of SCS for treating PDN in the lower extremities (evidence level: 1B+). Acupuncture and injection of botulinum toxin-A showed relief in pain or muscle cramps due to PDN with minimal side effects at an evidence level of 2B+/1B+. Surgical decompression of lower limb peripheral nerves for individuals with intractable PDN and superimposed nerve compression yielded an evidence level of 2B±/1B+. Sympathetic blocks or neurolysis and dorsal root ganglion (DRG) stimulation were limited to case series, resulting in an evidence level of 2C+. The authors concluded that moderate to strong evidence exists to support the utilization of SCS for managing lower extremity pain in individuals who have failed conventional medical management (CMM) for PDN. For individuals with PDN superimposed with nerve compression, surgical decompression of the peripheral nerves may be considered. As adjunctive therapy for PDN, acupuncture or injection of botulinum toxin-A can be considered. The review showed moderate to strong evidence supporting the use of SCS for managing lower extremity pain for individuals who have failed conservative medical management for PDN.

In 2022, D'Souza and associates evaluated the current body of literature looking for evidence on neuromodulation interventions for PDN in individuals with refractory PDN unresponsive to conventional medical management. The authors uncovered level 1 evidence supporting using 10-kHz and tonic dorsal column SCS. Other neuromodulation modalities, such as burst SCS, DRG, and peripheral nerve stimulation, are still limited with evidence levels of II-3, III, and II-3, respectively. The authors concluded that the literature shows how individuals undergoing 10-kHz SCS for treating PDN presented improvements in neurological physical examination, sensory testing, and/or reflex testing in individuals experiencing 10-kHz (level of evidence: I).

Henson et al. (2021) performed a systematic review to examine the evidence and outcomes related to SCS for PDN . Fourteen studies were reviewed. Two of the studies were randomized controlled trials with 6-month follow-up, one study provided additional analysis of the randomized controlled trial (RCT) quality of life (QoL) data, and the remainder were prospective observational studies. The authors reported that in the two randomized controlled trials, there was a clinically and statistically significant improvement in lower extremity pain and QoL for individuals who received SCS therapy. All observational studies examined also demonstrated significant improvement in pain. The authors concluded that there was moderate-quality evidence for the safety and efficacy of SCS for PDN. All randomized controlled trials analyzed were determined to have a significant risk of bias due to their unblinded design. The duration of follow-up for both randomized controlled trials analyzed was only 6 months, which may not have been adequate to assess the long-term effectiveness of this therapy.

Duarte et al. (2021) conducted a systematic review and meta-analysis on individual patient data from RCTs to assess the effectiveness of SCS for the management of PDN. Two eligible RCTs (total of 93 patients) and 2 long-term follow-up studies of one of the RCTs. Meta-analysis showed reductions in pain intensity for SCS compared with best medical therapy alone, on a 10-point scale at the 6-month follow-up. More patients receiving SCS achieved at least a 50% reduction in pain intensity compared with best medical therapy. Increases were observed for health-related QoL assessed as EuroQol 5-Dimension Questionnaire (EQ-5D) utility score and visual analogue scale (VAS). The authors concluded that the findings demonstrated that SCS is an effective therapeutic adjunct to best medical therapy in reducing pain intensity and improving health related QoL for individuals with PDN. Large well-reported RCTs with long-term follow-up are required to confirm these results.

Petersen et al. (2021) conducted a prospective, multicenter, open-label SENZA-PDN randomized clinical trial to compare CMM with 10-kHz SCS plus CMM for patients with refractory PDN. The study included 216 participants with 103 randomized to CMM and 113 assigned to 10-kHz SCS plus CMM. The mean VAS score decreased in the 10 kHz SCS group from 7.6 cm at baseline to 1.7 cm at six months, corresponding to 78% pain relief. The mean pain scores for the CMM group decreased from 7.0 cm at baseline to 6.9 cm at six months. Pain worsened in 48 CMM participant (52%) and 2 SCS participant (2%) after six months. The responder rate (≥ 50% pain relief) was significantly higher in the 10 kHz SCS arm (85%) than the CMM treatment arm (5%) and the pain remission rate was 60% in the 10 kHz SCS group and 1% in CMM group. The baseline mean score on the Douleur Neuropathique 4 (DN4) questionnaire was used to assess the neuropathic nature of pain in the study participant. The mean DN4 decreased from 6.5 at base line to 3.5 at six-month follow-up in the 10 kHz SCS group. There was an increase from 6.4 at baseline to 6.6 at six months in the mean DN4 score of the control group. At six months, three patients in the CMM group (3%) and 52 in the 10 kHz SCS group (62%) demonstrated neurological improvements over baseline. Sleep disturbances due to pain increased by 5.3% in the CMM group while decreasing 61.9% in the 10 kHz SCS group. The authors concluded that substantial pain relief and improved health-related QoL sustained over 6 months demonstrates 10-kHz SCS can safely and effectively treat patients with refractory PDN. Patients with PDN with inadequate pain relief despite best available medical treatments should be considered for 10-kHz SCS.

A multi-center retrospective analysis of data extracted from a commercial real-world database of patients with painful diabetic peripheral neuropathy (pDPN) who were trialed and permanently implanted with a 10 kHz SCS device was performed by Chen et al. (2021). Patients (n = 89) were assessed for baseline prior to 10 kHz SCS trial and at regular follow-up visits after device implantation. Percentage of pain relief was reported at each follow-up visit. Successful response to 10 kHz SCS was defined as at least 50% patient-reported pain relief. Patients were also asked about changes in sleep and improvement in overall function. The average time of follow-up was 21.8 months. Most patients (78.7%) identified pain primarily in their feet or legs bilaterally. At the last assessment, 79.5% of patients reported as having at least 50% pain relief from baseline. The average reduction in pain during the assessment period was 60.5%. A majority reported improved sleep (78.5%) as well as improved function (76.0%). Eighty-five percent of patients reported at least 50% pain relief was maintained over 12 months. Twenty-seven patients had completed 24-month follow-up post-implant and 88.9% continued to report at least 50% pain relief compared to baseline. The authors concluded that this study found 10 kHz SCS provided meaningful pain relief for a substantial proportion of patients' refractory to current pDPN management and could provide an alternative pain management approach. Limitations of the study include its retrospective nature and lack of randomization.

Chronic Intractable Back Pain Without Prior Spine Surgery

A 2022 ECRI report focused on how Senza compared with conventional medical management (CMM) and other spinal cord stimulation (SCS) systems for treating chronic back, leg, and arm pain. Evidence from one systematic review with network meta-analyses and two randomized controlled trials showed that Senza was safe and reduced pain by more than 50% for up to one year in patients with chronic pain compared with CMM. The authors found that the studies in the SR were at high risk of bias from three or more of the following: small sample size, retrospective design, single-center focus, and lack of randomization and control groups. The SR included studies of patients with different pain (ECRI, 2022).

Kapural et al. (2022) conducted a multicenter, randomized controlled trial (RCT) to compare CMM with and without 10-kHz SCS in individuals with nonsurgical refractory back pain (NSRBP). Primary and secondary endpoints included the responder rate (≥ 50% pain relief), disability (Oswestry Disability Index [ODI]), global impression of change, quality of life (QoL) EuroQol 5-Dimension Questionnaire (EQ-5D-5L) and change in daily opioid use and were analyzed at 3 and 6 months. The protocol allowed for an optional crossover at 6 months for both arms, with observational follow-up over 12 months. One hundred and fifty-nine individuals with NSRBP were included in the study. Seventy-six patients received CMM, and 69 patients who were assigned to the 10-kHz SCS group received a permanent implant. At the 3-month follow-up, 80.9% of patients who received stimulation and 1.3% of those who received CMM reported improved pain scores (≥ 50% reduction in visual analog scale [VAS]), functional status (≥ 10-point reduction in ODI scores), and patient-perceived symptom improvement (Patient's Global Impression of Change [PGIC]) and QoL (EQ-5D-5L scores). At 6 months in the 10-kHz SCS arm, outcomes were sustained. In the CMM arm, 74.7% of patients met the criteria for crossover and received an implant. The crossover arm obtained a 78.2% responder rate 6 months postimplantation. Five serious adverse events (AEs) occurred. The authors concluded that the addition of 10-kHz SCS to CMM resulted in improvements in pain relief, function, QoL, (This trial is included in the ECRI, 2022) report).

A systematic review was performed by Eckermann et al. (2021) to identify studies reporting outcomes for SCS in chronic back pain patients (with or without secondary radicular leg pain) without prior surgery. The primary outcomes measured were the

magnitude of change in pain from baseline to follow-up, the proportion of subjects achieving a 50% reduction in pain, and AEs related to the device or procedure. Outcome measures related to improvements in QoL, disability, function, and changes in medication use were also evaluated. A total of ten studies were included (including a total of 357 patients). Final follow-up periods across all studies ranged from 12 to 36 months. In a majority of studies, reductions in pain were observed as early as 3 months after treatment, with reductions in pain also evidenced at 6, 9, 12, 24, and 36 months postintervention. The authors reported that the studies demonstrated favorable outcomes in terms of pain reduction and functional improvement following SCS therapy. Improvements also occurred in quality-of-life scores; however, not all studies reported statistically significant findings. The studies reported that SCS resulted in high patient satisfaction, reductions in opioid use, and an acceptable safety profile, although these data were more limited. The authors concluded that SCS is a promising, safe, minimally invasive, and reversible alternative option for managing chronic back pain in patients who have not undergone spinal surgery. The studies were predominantly observational with relatively small sample sizes, and many studies did not have a comparison or control group.

Baranidharan et al. (2021) performed a prospective, single center, open label trial to explore the use of SCS in patients with associated allodynia and hyperalgesia. Twenty-one individuals with back pain and hyperalgesia or allodynia who had not had prior spinal surgery underwent a SCS trial followed by full implantation. Patients attended follow-up visits after 6 and 12 months of SCS. Repeated measure ANOVAs/Friedman tests explored change after 6 and 12 months of 10 kHz SCS. Independent sample t-tests/Mann-Whitney U tests examined differences in response after 12 months. The authors reported that compared to baseline, 12 months of 10 kHz SCS was associated with improvements in back and leg pain, health-related QoL, pain-related disability and medication consumption. After 12 months of treatment, 52% of patients had ≥ 50% improvement in back pain, 44% achieved remission for back pain, 40% reported ODI scores between 0 and 40 and 60% experienced a reduction of at least 10 ODI points. Limitations of this study included a small sample size, short follow-up period, and no control group (This trial is included in the Eckermann, (2021) study).

A prospective, multicenter, RCT (SENZA-RCT) was conducted by Amirdelfan et al. (2018). Patients with both chronic intractable back and leg pain were enrolled and randomized (1:1) into 10 kHz SCS or traditional SCS treatment groups. A total of 171 subjects received a permanent SCS device implant. QoL and functionality measures were collected up to 12 months. At 12 months, in the 10 kHz SCS group, 69.6% of the individuals had an improved ODI score. Individuals reported better improvement in the Global Assessment of Functioning, Clinician Global Impression of Change, Pittsburgh Sleep Quality Index, and short-form McGill Pain Questionnaire, compared to traditional SCS participants. The authors concluded that in addition to superior pain relief, 10 kHz SCS provided long-term improvements in QoL and functionality for patients with chronic low-back and leg pain. The study was limited by the heterogeneity of pain diagnoses and lack of masking to the assigned treatment group (This trial is included in the ECRI 2022 report).

Refractory Angina Pectoris

A single center prospective observational study was performed by Vervaat et al. (2020) to show the effects of spinal cord stimulation (SCS) on the severity of angina complaints and quality of life (QoL). Eighty-seven patients with refractory angina pectoris (RAP) received SCS. Ninety-two percent had angina pectoris CCS class III or IV. Ischemia was proven by MIBI-SPECT in 69%. The Seattle Angina Questionnaire (SAQ) and RAND 36-Item Health Survey (RAND-36) were completed at baseline, prior to implantation, and 1-year post-implantation. After 1 year of follow-up there was a decrease in the frequency of angina pectoris attacks from more than 4 times a day to 1-2 times a week ($p < 0.001$). The SAQ showed improvement in four of the five dimensions: physical limitation ($p < 0.001$), angina frequency ($p < 0.001$), angina stability ($p < 0.001$) and QoL ($p < 0.001$). The improvement in satisfaction with treatment was not statistically significant ($p = 0.55$). The RAND-36 showed improvement in all nine dimensions: physical functioning ($p = 0.001$), role/physical ($p < 0.001$), social functioning ($p = 0.03$), role/emotional ($p < 0.05$), bodily pain ($p < 0.001$), general health ($p < 0.001$), vitality ($p < 0.001$), mental health ($p = 0.02$) and health change ($p < 0.001$). Secondary findings of this study were a reduction in the use of short-acting NTG use from 1–3 times a day to less than once a week, low cardiovascular mortality (1.1%) and low all-cause mortality (3.4%). The authors concluded that the study showed a significant improvement in QoL and reduction of angina pectoris severity after 1 year of follow-up in patients treated with SCS for RAP. This was a nonrandomized study design without a control group.

Pan et al. (2017) conducted a systematic review and meta-analysis to evaluate the efficacy and safety of conventional SCS in the treatment of RAP. Five meta-analyses were performed examining the changes in Canadian Cardiovascular Society classes, exercise time, Visual Analog Scale (VAS) scores of pain, Seattle Angina Questionnaire, and nitroglycerin use in RAP patients after SCS therapy. Twelve randomized controlled trials involving 476 RAP patients were included. The results identified reduction in the angina frequency and nitroglycerin consumption in the SCS group. Compared with the control group, SCS

showed benefit on increasing exercise time and treatment satisfaction with decreased VAS scores of pain and disease perception. The result did not reach the significance level in terms of physical limitation (p = 0.39) or angina stability (p = 0.50). The authors concluded that SCS relieves the symptoms of angina pectoris without increasing the nitroglycerin consumption to some extent. Future larger outcome studies for finding the appropriate intensity of stimulation are needed.

A systematic review and meta-analysis were conducted by Imran et al. (2017) to examine whether SCS is associated with changes in exercise capacity and angina severity. Fourteen studies with 518 participants were included. SCS implant duration ranged from 3 weeks to 5 years (median: 6 months). The results found that SCS was associated with a higher exercise duration and lower angina severity, 1.55 less daily angina episodes, 1.54 less daily nitrates consumed, and a 22 points higher SF-36 angina frequency score on follow-up. The authors concluded that SCS, as an adjunct therapy to medical management, may be associated with a longer exercise duration and lower angina frequency and nitrate consumption in patients with chronic RAP who are not candidates for percutaneous intervention or revascularization. Further studies, including randomized trials with a long-term follow-up, are needed to validate these findings.

Tsigaridas et al. (2015) conducted a systematic review of randomized controlled trials (RCTs) to investigate the effectiveness of SCS as a treatment for refractory angina. Nine RCTs were categorized into two groups: RCTs comparing SCS either with optimal medical treatment or inactive mode or low stimulation SCS; and those comparing SCS with alternative therapeutic interventions. Follow-up was 1-6 months in most studies, showing no major complications. Two studies reported a neutral effect regarding mortality. The most recent, multi-center RCT reported no significant difference compared to the control group. The authors concluded that RCTs investigating the efficacy of SCS were small and they demonstrated a small effect in angina improvement. Larger, well-designed, multicenter RCTs are needed with longer follow-up.

Dorsal Root Ganglion (DRG) Stimulation

In 2022, Moman and colleagues led a systematic review and pooled analysis to decide the overall incidence of DRGs infections, occurrence at each stage, infection characteristics, and outcomes. Out of the ten studies that met inclusion criteria, eight reported on individuals with trial data, resulting in 291 individuals; ten articles reported on those with implant data, resulting in 250 individuals; and lastly, articles that reported on revisions resulted in twenty-six individuals. The pooled incidence of trial infections was 1.03% (95% CI 0.35-2.99%), implant infections was 4.80% (95% CI 2.77-8.20%), revision infections results were 3.85% (95% CI 0.20-21.59%), and overall infections results were 2.82% (95% CI 1.62-4.54%). There was a statistically significant difference in infection rates between the trial, implant, and revision stages, X2 (2, n = 567) = 8.9839, p = 0.01. The results prove the DRG's trials appear to be low risk for infection however, the risk is increased when the DRG is implanted. The authors conclude there is a need for further studies on infectious complications, risks, and best prophylaxis.

Hagedorn et al. (2022) conducted a systematic review and meta-analysis to find the number of individuals satisfied with using spinal cord stimulation (SCS) and DRG-S for treating chronic intractable pain. The authors uncovered 242 citations, including nine randomized controlled trials (RCTs), and 23 observational studies, resulting in the utilization of 25 studies comprising 1,355 individuals. A quantitative analysis was conducted, and the pooled portion of individuals who reported satisfaction from all obtained articles was 82.2% (95% CI, 77.8%-86.2%), which had a high statistical heterogeneity (I2 = 74.0%). The subgroup analysis revealed no differences in satisfaction when articles were stratified according to study design or follow-up period. The author’s concluded individuals are highly satisfied with SCS and DRG-S when the treatment modalities are utilized for chronic intractable pain. Limitations include the scarcity of unbiased and/or non-industry-funded prospective studies, and future efforts to expand this area of SCS and DRG-S literature are necessary.

Stelter et al. (2021) conducted a systematic review of clinical studies demonstrating the use of DRGS for non-CRPS-related chronic pain syndromes. A total of twenty-eight studies comprising 354 total patients were included in the review. Of the chronic pain syndromes presented, axial low back pain, chronic pelvic and groin pain, and other peripheral neuropathies, a majority demonstrated > 50% mean pain reduction at the time of last follow-up. Physical function, quality of life (QOL), and lesser pain medication usage also were reported to be significantly improved. The authors concluded that evidence from lower-level studies did show success with the use of DRGS for various non-CRPS chronic pain syndromes in reducing pain along with increasing function and QOL from one week to three years. DRGS continues to lack supportive evidence from well-designed, high-level studies and recommendations from consensus committee experts.

A systematic review was conducted by Nagpal et al. (2021) to evaluate the effectiveness of DRG neurostimulation for the treatment of refractory, focal pain in the pelvis and lower extremities. The primary outcome was ≥ 50% pain relief. Secondary outcomes were physical function, mood, QoL, opioid usage, and complications. One randomized controlled trial, four

prospective cohort studies, and eight case series were included in the review. The RCT reported ≥ 50% pain relief in 74% of patients with DRG neurostimulation vs. 51% of patients who experienced at least 50% relief with SCS at 3 months. Cohort data success rates ranged from 43% to 83% at ≤ 6 months and 27% to 100% at > 6 months. Significant improvements were also reported in the secondary outcomes assessed, including mood, QoL, opioid usage, and health care utilization, though a lack of available quantitative data limited further statistical analysis. The only RCT reported a higher rate of adverse events (AEs) than that seen with traditional neurostimulation. The authors concluded that low-quality evidence supported DRG neurostimulation as a more effective treatment than traditional neurostimulation for pain and dysfunction associated with complex regional pain syndrome (CRPS) or causalgia. Very low-quality evidence supported DRG neurostimulation for the treatment of chronic pelvic pain, chronic neuropathic groin pain, phantom limb pain, chronic neuropathic pain of the trunk and/or limbs, and diabetic neuropathy (DPN).

A 2021 Hayes health technology assessment was conducted to evaluate the safety and effectiveness of DRG stimulation for the treatment of CRPS in adults with CRPS in the lower extremities. The literature search identified 5 studies that met the inclusion criteria; one RCT compared DRG stimulation with spinal cord stimulation SCS after 12 months of treatment, three pretest-posttest studies assessed outcomes in terms of change from baseline (CFBL) following 3 to 12 months of treatment with DRG stimulation., and a retrospective chart review assessed outcomes during the post implantation period in patients undergoing DRG stimulation. The authors concluded that a limited evidence base suggests that DRG stimulation may be associated with treatment success and improved outcomes for pain, QOL, and mood compared with baseline levels or SCS treatment. Two studies suggested that treatment benefits associated with DRG stimulation were observed for patients with CRPS type I and type II. Well-designed comparative studies are needed to evaluate comparative benefits versus harms. The effectiveness and safety of DRG stimulation for the treatment of neuropathic pain associated with other chronic pain etiologies (e.g., cancer; postherpetic neuralgia; DPN; central neuropathic pain due to multiple sclerosis, stroke, ischemia, or amputation) are unknown (Hayes, 2021).

A 2021 ECRI clinical evidence assessment focused on Proclaim DRG Neurostimulation System's safety and effectiveness for treating CRPS. The report included one RCT, 1 within-subjects comparative study, and 5 case series and found low-strength, but conclusive evidence that DRG with Proclaim relieves pain as much or more than SCS at up to 3-month follow up for in patients with CRPS. Larger, multicenter studies reporting on 1- to 5-year outcomes are needed to confirm Proclaim's effectiveness for treating CRPS. The RCT was at risk of bias from lack of blinding. The other included studies were at high risk of bias from lack of independent controls and small sample sizes.

Horan et al. (2021) performed an observational, multicenter cohort study of all patients in Denmark implanted with FDA-approved DRG stimulation systems to treat chronic, neuropathic pain between 2014 and 2018. Follow-up period was one to three years. Forty-three patients underwent trial DRG stimulation; 33 were subsequently fully implanted. Pain location: 58% lower extremity; 21% upper extremity; 21% thoracic/abdominal. At the end of the observation period, 58% of fully implanted patients were still implanted; 42% had fully functional systems. In these patients, average Numerical Rating Scale (NRS)-score of pain was reduced from 6.8 to 3.5 and worst NRS-score was reduced from 8.6 to 6.0 at 12 months follow-up. Pain Catastrophizing Score was reduced from 32 to 15. Thirteen patients experienced complications related to defect leads (39% of implanted systems). In four patients (12%), lead removal left fragments in the root canal due to lead fracture, and three patients suffered permanent nerve damage during attempts to replace broken leads. The authors concluded that this study suggested a significant, clinically relevant effect of DRG stimulation on neuropathic pain, but also demonstrates substantial problems with maintenance and revision of currently available systems. This is an uncontrolled study with a small sample size. Additional multi-center, prospective, randomized trials with longer follow-up are still needed to elucidate DRG's role in the treatment of peripheral nerve injury (PNI).

Kretzschmar et al. (2021) conducted a retrospective chart review of patients who underwent DRG stimulation for the treatment of chronic neuropathic pain after PNI at a single German center between January 2013 and December 2015. Twenty-seven patients were trialed with a DRG neurostimulation system for PNI; trial success (defined as ≥ 50% pain relief) was 85%, and 23 patients received a permanent stimulator. Thirty-six-month outcome data was only available for 21 patients. Pain, QoL, mental and physical function, and opioid usage were assessed at baseline and at 3-, 6-, 12-, 18-, 24-, and 36 months post-permanent implant. Compared to baseline, a significant pain relief was noted at 3 (58%), 12 (66%), 18 (69%), 24 (71%), and 36 months (73%) in 21 patients respectively. Mental and physical function showed immediate and sustained improvements. Participants reported improvements in QoL. Opioid dosage reduced at 3 (30%), 12 (93%), 18 (98%), 24 (99%), and 36 months (99%), and 20 of 21 patients were completely opioid-free after 36 months. The authors concluded that DRG neuromodulation appeared to be

a safe, effective, and durable option for treating neuropathic pain caused by PNI. The study is limited by its retrospective observations and small sample size.

Kallewaard et al. (2020) performed a prospective, single-arm post-market pilot study to determine the effect of DRG stimulation for a group of patients with discogenic LBP with no history of previous back surgeries. Twenty subjects with confirmed discogenic LBP and no prior history of back surgery underwent trials of DRG stimulation and, if successful with at least 50% pain reduction, were permanently implanted. Subjects rated their pain, disability, QoL, and mood at baseline, and 14 subjects were followed through 12 months of treatment. Treatment with DRG stimulation reduced LBP ratings (68.3% reduction), from mean 7.20 at baseline to 2.29 after 12 months. Oswestry ratings of disability decreased from 42.09 at baseline to 21.54 after six months of treatment and to 20.1 after 12 months. The average QoL EuroQol 5-Dimension Questionnaire (EQ-5D) index score at baseline was 0.61 and 0.84 after 12 months. The authors concluded that DRG stimulation treatment for discogenic LBP improved the level of pain, function, and QoL. This study is limited by a small study population.

Mekhail et al. (2020) performed a retrospective analysis of therapy outcomes on 61 individuals in the ACCURATE study who received a permanent DRG neurostimulator. Outcomes of individuals who were paresthesia-free were compared to those who experienced paresthesia-present therapy at 1, 3, 6, 9, and 12-month follow-up. The percentage of individuals with paresthesia-free pain relief increased from 16.4% at 1-month to 38.3% at 12-months. Paresthesia-free subjects generally had similar or better outcomes for pain severity, pain interference, QoL, and mood state as subjects with paresthesia-present stimulation. Factors that increased the odds of an individual feeling paresthesia were higher stimulation amplitudes and frequencies, number of implanted leads, and younger age. The authors concluded that some DRG subjects achieved effective paresthesia-free analgesia in the ACCURATE trial, and this supported the observation that paresthesia is not synonymous with pain relief or required for optimal analgesia with DRG stimulation (This study is included in the Hayes 2021 report).

Neuromodulation Appropriateness Consensus Committee (NACC), an international, interdisciplinary work group conducted a systematic literature review of DRG stimulation for pain. Inclusion criteria were prospective trials (randomized controlled trials and observational studies). Studies were graded using the modified Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment, the Cochrane Collaborations Risk of Bias assessment, and the US Preventative Services Task Force level-of-evidence criteria. The group concluded that DRG stimulation has Level II evidence (moderate) based upon one high-quality pivotal RCT and two lower-quality studies. Moderate-level evidence supports DRG stimulation for treating chronic focal neuropathic pain and CRPS (Deer, 2020).

Huygen et al. (2020) conducted a meta-analysis to identify differences in outcome between chronic pain etiologic subgroups and/or pain location. One prospective, randomized comparative trial and six prospective, single-arm, observational studies were included. Pain scores and patient-reported outcome (PRO) measures were weighted by study sample sizes and pooled. The study included 217 patients with a permanent implant at 12-month follow-up. The analysis showed an overall weighted mean pain score of 3.4, with 63% of patients reporting ≥ 50% pain relief. Effectiveness sub-analyses in CRPS-I, causalgia, and back pain resulted in a mean reduction in pain intensity of 4.9, 4.6, and 3.9 points, respectively. The analysis showed a pain score for primary affected region ranging from 1.7 (groin) to 3.0 (buttocks) and responder rates of 80% for foot and groin, 75% for leg, and 70% for back. The most commonly reported complications were pain at the IPG pocket site, lead fracture, lead migration, and infection. The authors concluded that DRG stimulation is an effective therapy for multiple chronic pain disorders for patients that have failed to receive pain relief and QoL improvements from other interventions. Data of most patients in the analysis came from industry sponsored studies. Further research with randomized controlled trials is needed to validate these findings.

A systematic review about patient selection, efficacy, and safety of neuromodulation with electrical field stimulation (EFS) DRG in various painful conditions was conducted by Vuka et al. (2019). Twenty-nine studies were included, one RCT, case series, and case reports. Included studies analyzed the following painful conditions: CRPS, LBP, groin pain, pelvic girdle pain, peripheral neuropathy, peripheral DPN, phantom limb pain, chronic intractable pain in the coccyx, chronic testicular pain, anterior cutaneous nerve entrapment syndrome (ACNES), loin pain hematuria syndrome (LPHS). CRPS was the most common indication treated. The evidence is based on studies with small number of participants (median: 6, range 1-152). Neuromodulation with EFS of DRG was mostly performed in participants who have failed other treatment modalities. Most of the authors of the included studies reported positive, but inconclusive, evidence regarding efficacy of neuromodulation with EFS of DRG. Meta-analysis was not possible since only one RCT was included. The most common SAE related to stimulation was overstimulation. The authors concluded that the evidence suggested that neuromodulation with EFS of DRG may help highly selected participants with various pain syndromes, who have failed to achieve adequate pain relief with other

pharmacological and nonpharmacological interventions. Study limitations included poor quality of studies, very small number of participants included, highly selected patient population, and conflict of interest of sponsors and authors.

Deer et al (2017) conducted a prospective, multicenter, randomized comparative effectiveness trial (known as the ACCURATE trial) in 152 subjects diagnosed with CRPS or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column. The primary end point was a composite of safety and efficacy at 3 months, and subjects were assessed through 12 months for long-term outcomes and AEs. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in visual analog scale (VAS) score from pre-implant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥ 50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%) at 3 months. Device-related and serious AEs were not different between the 2 groups. DRG stimulation also demonstrated greater improvements in QOL and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia and reduced extraneous stimulation in non-painful areas, indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. The researchers concluded that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS. Additional prospective randomized trials with longer follow-up are still needed to clarify the safety and efficacy of DRG in patients with CRPS or causalgia (This study is included in the Hayes 2021 report).

Schu et al. (2015) conducted a retrospective review of data from patients with groin pain of various etiologies treated using neuromodulation of the DRG. Twenty-nine patients with neuropathic groin pain were reviewed. Pain scores were captured on a VAS at baseline and at regular follow-up visits. Twenty-five patients (86.2%) received fully implantable neurostimulators, and the average follow-up period was 27.8 ±4.3 weeks. The average pain reduction was 71.4 ±5.6%, and 82.6% (19/23) of patients experienced a > 50% reduction in their pain at the latest follow-up. Individual cases showed improvement with a variety of etiologies and pain distributions; a sub analysis of post-herniorrhaphy cohort also showed significant improvement. The authors concluded that early findings suggest that neuromodulation of the DRG may be an effective treatment for chronic neuropathic pain conditions in the groin region. This technique offers a useful alternative for pain conditions that do not always respond optimally to traditional SCS therapy. Neuromodulation of the DRG provided excellent cross-dermatomal paresthesia coverage, even in cases with patients with discrete pain areas. The therapy can be specific, sustained, and independent of body position. Study limitations include non-randomization and small sample size.

Clinical Practice Guidelines

American College of Cardiology Foundation/American Heart Association Task Force (ACCF/AHA)

In 2013, Anderson et al. reported on the ACCF/AHA guidelines for managing individuals with unstable angina/non-ST elevated myocardial infarctions. Regarding spinal cord stimulation (SCS), the guidelines read: “Other less extensively studied therapies for relieving ischemia, such as SCS and prolonged external counterpulsation, are under evaluation. Most experience has been gathered with SCS in ‘intractable angina’ in which anginal relief has been described. They have not been applied in the acute setting for UA/NSTEMI.”

American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society (AHA/ACC/HRS)

In 2018, Al-Khatib et al. reported that the AHA/ACC/HRS found limited data on the role of vagal nerve stimulators and SCS in the prevention of VA/SCD; therefore, no formal recommendation has been supported.

Department of Veterans Affairs Department of Defense (VA/DoD)

A 2022 VA/DoD Clinical Practice Guideline for the diagnosis and treatment of low back pain recommended against SCS for patients with low back pain.

National Institute for Health and Care Excellence (NICE)

In 2019, NICE supplied recommendations for the Senza SCS system for delivering HF10 therapy to treat chronic neuropathic pain. The recommendations are as follows:

- The case for adopting Senza SCS for delivering HF10 therapy as a treatment possibility for chronic neuropathic back or leg pain after the evidence supports failed back surgery. HF10 therapy using Senza SCS is at least as effective as low-frequency SCS in reducing pain and functional disability and avoids the experience of tingling sensations (paresthesia).

- Senza SCS for delivering HF10 therapy should be considered for individuals:
  - With residual chronic neuropathic back or leg pain (at least 50 mm on a 0 mm to 100 mm visual analog scale [VAS]) at least six months after back surgery despite conventional medical management (CMM) and
  - Who has had a successful stimulation trial as part of a more comprehensive assessment by a multidisciplinary team.
- Individuals with other causes of neuropathic pain were included in the evaluation and may be considered for HF10 therapy using Senza SCS but any added benefits compared with low-frequency SCS are less specific. Cost modeling shows that over 15 years, HF10 therapy using Senza SCS has similar costs to low-frequency SCS using either a rechargeable or non-rechargeable device.
- Clinicians implanting SCS devices, including Senza, should send prompt and complete data to the UK Neuromodulation Registry.
- When assessing the severity of pain and the stimulation trial, the multidisciplinary team should be aware of the need to ensure equal access to treatment with SCS. Tests to assess pain and response to SCS should consider a person's disabilities (such as physical or sensory disabilities) or linguistic or other communication difficulties and may need to be adapted.

According to NICE, 2008 the guidance on SCS reads as follows:
- SCS is recommended as a treatment possibility for adults with chronic pain of neuropathic origin who:
  - Continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm VAS) for at least six months despite proper conventional medical management, and
  - Who have had a successful stimulation trial as part of the assessment specified in the recommendation.
- SCS is not recommended as a treatment possibility for adults with chronic pain of ischemic origin except in the context of research as part of a clinical trial. Such research should be designed to generate robust evidence about the benefits of SCS (including pain relief, functional outcomes, and quality of life) compared with standard care.
- SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with SCS devices, including experience in the provision of ongoing monitoring and support of the person assessed.
- When assessing the severity of pain and the stimulation trial, the multidisciplinary team should be aware of the need to ensure equal access to treatment with SCS. Tests to assess pain and response to SCS should consider a person's disabilities (such as physical or sensory disabilities) or linguistic or other communication difficulties and may need to be adapted.
- If different SCS systems are equally suitable for a person, the least costly should be used. Assessment of cost should consider acquisition costs, the predicted longevity of the system, the stimulation requirements of the person with chronic pain, and the support package offered.
- People who are currently using SCS for treating chronic pain of ischemic origin should have the choice to continue treatment until they and their clinicians consider it right to stop.

North American Spine Society (NASS)

The 2020 NASS Evidence Based Clinical Guideline for the diagnosis and treatment of low back pain systematic review of the literature yielded no studies to adequately address electrical stimulation for low back pain.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Implantable spinal cord stimulation systems for pain relief are regulated by the FDA as Class III devices and are approved through the Premarket Approval (PMA) process. Refer to the following website for more information (use product codes LGW, GZB, GZF): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed October 17, 2022)

There are several devices used for DRG stimulation. Refer to the following website for more information and search by product code PMP: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed October 17, 2022)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2023	Coverage Rationale *Implanted Electrical Spinal Cord Stimulators* • Revised language to indicate:

Date	Summary of Changes
	○ Implanted electrical spinal cord stimulators are proven and medically necessary for treating the following conditions in certain circumstances, when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions: ▪ Complex regional pain syndrome (CRPS) ▪ Painful lower limb diabetic neuropathy ▪ Failed back surgery syndrome ○ Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating the following conditions due to insufficient evidence of efficacy: ▪ Chronic intractable back pain without prior spine surgery ▪ Refractory angina pectoris *Dorsal Root Ganglion (DRG) Stimulation* • Added language to indicate: ○ Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) in certain circumstances when performed according to U.S. FDA labeled indications, contraindications, warnings, and precautions ○ Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other conditions [not list as proven and medically necessary] due to insufficient evidence of efficacy Applicable Codes • Added CPT code 63650 • Added notation to indicate HCPCS codes C1816, C1820, C1822, C1823, C1883, C1897, L8679, L8680, L8682, L8685, L8686, L8687, and L8688 are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program Supporting Information • Added *Clinical Evidence* and *References* sections • Updated *FDA* section to reflect the most current information • Archived previous policy version CS061LA.R

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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