Implanted Electrical Stimulator for Spinal Cord (for Tennessee Only)

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Instructions for Use

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- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only)
- Gastrointestinal Motility Disorders, Diagnosis and Treatment (for Tennessee Only)
- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

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

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

Click here to view the InterQual® criteria.

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

Click here to view the InterQual® criteria.

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

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, requiring pocket creation and connection between electrode array and pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array

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HCPCS Code	Description
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

Clinical Evidence

Chronic Intractable Back Pain Without Prior Spine Surgery

The Dorsal Spinal Cord Stimulation vs Medical Management for the Treatment of Low Back Pain (DISTINCT) study is a multicentered, prospective randomized controlled trial that evaluated the efficacy of spinal cord stimulation (SCS) compared with that of conventional medical management (CMM) in improving pain and back pain-related physical function in patients with chronic, refractory axial low back pain (PSPS type 1), who had not undergone lumbar surgery and for whom surgery was not an option (Deer et al., 2023). The study enrolled 270 individuals who were randomized to passive recharge burst therapy (n = 162) or CMM (n = 107). They reported severe pain and disability for more than a decade and had failed a multitude of therapies. Individuals were seen for required study visits at one, three, and six months. The primary end point reported improvements in pain intensity. In an intension to treat (ITT) analysis, 73.1% of subjects randomized to SCS responded with 50% greater pain relief compared with 6.2% randomized to CMM. An analysis of subjects receiving stimulation per treatment evaluation (PTE) at six-month follow-up showed 85% responded compared with 6.2% of subjects with CMM. A composite measure on function or pain relief showed 91% of subjects with SCS improved, compared with 16% of subjects with CMM. An improvement of 30 points was observed on Oswestry disability index (ODI) compared with a < one-point change in the CMM arm. Three serious and 14 non-serious device- or procedure-related events were reported. No serious events were reported in the CMM group. The

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treatment arm decreased from a score of 52.5 ±13.8, indicating severe disability, at baseline to a moderate disability score of 22.6 ±13.8 at six months. Individuals with CMM reported severe disability at baseline (53.2 ±14.6) but remained severely disabled after six months of treatments (53.6 ±18.1). A total of 88.2% of subjects with burst spinal cord stimulation (B-SCS) reported meaningful changes on the psychologic PCS instrument compared with 23.5% of subjects with CMM. The authors concluded that this study found substantial improvement at six months in back pain, back pain-related disability, pain-related emotional suffering, pain interference, and physical function in a population with severe, debilitating back pain for more than a decade. They reported improvements in conjunction with reduced opioid use, injection, and ablation therapy. The short-term follow-up did not allow for assessment of intermediate and long-term outcomes. Limitations of the study include manufacturer sponsored and lack of blinding of study subjects, physicians, or study site personnel to the treatment assignment, Long-term studies are required to verify sustained results.

A prospective, single-arm, single-center, post-market, pilot study was performed by Mons et al. (2023) to evaluate the effect of B-SCS in the management of chronic discogenic (CD) pain in subjects who are refractory to other available treatments. Fifteen individuals were included in the study. The patients rated lower back pain (LBP) and leg pain using the numeric rating scale (NRS), ODI, patient global impression of change (PGIC), EQ-5D quality of life, and painDETECT for neuropathic pain at baseline following trial, 3, 6, and 12 months after permanent implantation. The study reported that treatment with B-SCS resulted in significant reduction of LBP as the NRS was reduced from 71.7 ±7.3 at baseline to 42.5 ±18.1 at 12 months. Average pain relief at 12 months was 42.5%. In patients with leg pain (n = 8), pain was reduced from 66.9 ±8.2 to 11.7 ±10.4 at 12 months. PainDETECT scores for neuropathic pain reduced from 18.9 ±4.8 at baseline, and 14.8 ±3.2 at 12 months. Baseline ODI score reduced from 41.2 ±12.8 to 25.8 ±8.6 at 12 months. PGIC scores remained low from 2.6 ±1.6 at 3 months, 2.5 ±1.0 at 6 months, and 2.5 ±1.3 at 12 months. EQ-5D-5L rates remained constant from baseline 56.10 ±23.9 to 68.6 ±12.9 at 12 months. The authors concluded that B-SCS resulted in significant reduction of back pain, leg pain, and quality of life in patients with CD-LBP and decreased the level of disability and generated positive patient satisfaction scores. Limitations of this prospective study is the open-label design and small subject population.

A 2022 ECRI report focused on how Senza compared with CMM and other 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, 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 (ODI), global impression of change, quality of life (QoL) - 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 (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 post implantation. 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

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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 SCS on the severity of angina complaints and 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. The SAQ showed improvement in four of the five dimensions: physical limitation, angina frequency, angina stability, and QoL. The improvement in satisfaction with treatment was not statistically significant. The RAND-36 showed improvement in all nine dimensions: physical functioning, role/physical, social functioning, role/emotional, bodily pain, general health, vitality, mental health, and health change. 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, VAS scores of pain, Seattle Angina Questionnaire, and nitroglycerin use in RAP patients after SCS therapy. Twelve RCTs 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

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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.

Dorsal Root Ganglion (DRG) Stimulation

Ghorayeb et al. (2023) conducted a systematic review to investigate the clinical use and effectiveness of DRGS for patients with chronic pelvic pain (CPP). The primary outcome of interest was the percent reduction in pain symptoms post-DRGS implantation. Secondary outcomes including QOL measurements and pain medication use. A total of nine studies comprising 65 total patients with variable pelvic pain etiologies met the inclusion criteria. The majority of subjects implanted with DRGS reported > 50% mean pain reduction at variable times of follow-up. Secondary outcomes reported throughout studies including quality of life (QOL) and pain medication consumption were reported to be significantly improved. The authors concluded that dorsal root ganglion stimulation for CPP continues to lack supportive evidence from well-designed, high-quality studies and recommendations from consensus committee experts. The available studies at this time are of low quality with a high risk of bias.

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%, implant infections was 4.80%, revision infections results were 3.85%, and overall infections results were 2.82%. 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 authors concluded that the results proved the DRG's trials appear to be low risk for infection however, the risk is increased when the DRG is implanted. Further studies on infectious complications, risks, and best prophylaxis are needed.

Hagedorn et al. (2022) conducted a systematic review and meta-analysis to find the number of individuals satisfied with using SCS and DRG-S for treating chronic intractable pain. The authors uncovered 242 citations, including nine 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%, 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 authors 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.

In a multicenter, crossover, nonblind randomized controlled study (Mol et al., 2022), DRG stimulation was compared with CMM (noninvasive treatments, such as medication, transcutaneous electric neurostimulation, and rehabilitation therapy) in patients with postsurgical inguinal pain (PSIP) that was resistant to a neurectomy. Eighteen patients were randomized (DRG and CMM groups each had nine patients). Six patients with CMM (67%) crossed over to DRG stimulation at six-months. Fifteen of the 18 patients met the six-month primary end point. Three patients with DRG stimulation had a negative trial and were lost to follow-up. Follow-up visits were completed at four weeks, three months, and six months. Of the 12 patients who received DRG stimulation, eight completed the six-month follow-up appointment, and a pain reduction of 50% was reported. In the CMM group, an increase in pain of 13% was reported. Patients in the DRG group experienced an improved quality of life and a decrease in pain interference, although group differences were not significant for these parameters. Nine patients with DRG stimulation experienced a total of 19 adverse events, such as lead dislocation and pain at the implantation site. No adverse events were reported for the CMM group. The authors concluded that DRG stimulation is a promising effective therapy for pain relief in patients with PSIP resistant to conventional treatment modalities, but larger studies are needed. This was a small cohort with a short-term follow-up.

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, 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

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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 RCT, 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 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). Based on a review of abstracts for the 2023 annual review, there were no newly published studies that meet the inclusion criteria set out in the report, which was published in 2021. The body of evidence is of very low quality. Limitations of individual studies included small sample sizes, retrospective study designs, lack of a comparator group, lack of power analyses, and high loss to follow-up (Hayes, 2023).

A 2021 ECRI clinical evidence assessment focused on Proclaim DRG Neurostimulation System's safety and effectiveness for treating CRPS. The report included one RCT, one within-subjects comparative study, and five 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 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

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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 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).

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.

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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 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).

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.

American Heart Association/American College of Cardiology/American College of Clinical Pharmacy/American Society for Preventive Cardiology/National Lipid Association/Preventive Cardiovascular Nurses Association (AHA/ACC/ACCP/ASPC/NLA/PCNA)

In a joint guideline for the management of patients with chronic coronary disease, Virani et al. (2023) stated that there are evidence gaps regarding the use of neuromodulation and thoracic spinal cord stimulation in patients with chronic coronary disease and refractory angina. The guideline committee recommended future research to address this treatment approach.

American Society of Regional Anesthesia and Pain Medicine (ASRAPM)

Shanthanna et al. (2023) created the ASRAPM evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation (SCS) for treatment of chronic non-cancer pain following a comprehensive literature review. The guidelines recommend that an SCS trial should be performed before a spinal cord stimulator is definitively implanted except when there is anginal pain. This recommendation supports the US Food and Drug Administration’s advisory that an SCS trial should be conducted before any implant due to the number of medical device reports on the failure of SCS to achieve or maintain adequate pain control. The guideline also recommends that all patients are screened with an objective, validated instrument for psychosocial factors including depression, and that patient selection criteria for SCS consider appropriate pain indication and patient determinants that can predict poor response to therapy.

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)

NICE evaluated the Evoke Spinal Cord Stimulator System for managing chronic neuropathic or ischemic pain in a 2020 Medtech innovation briefing and found that the evidence base was small with two studies (1 RCT and 1 observational study)

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that included 184 people, but that these studies included comparative evidence of good methodological quality. The experts that were consulted have stated that the device is likely to be comparable to other stimulator systems. The report stated that evidence showing equivalence between the open-loop Evoke system and other open-loop spinal cord stimulation devices used as standard care would be useful.

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.

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 either approved through the Premarket Approval (PMA) process or through the 510(K) process. Refer to the following website for more information (use product codes LGW, GZB): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Refer to the following website for more information about products that are approved through the 510(K) process (use product code GZF): 510(k) Premarket Notification (fda.gov). (Accessed October 4, 2023)

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 4, 2023)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2024	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; revised description for 63685 and 63688 **Supporting Information** • Archived previous policy version CS061TN.W

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