Implanted Electrical Stimulator for Spinal Cord (for North Carolina Only)

Policy Number: CSNCT0567.07
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➲ Instructions for Use

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Application

This Medical Policy only applies to the State of North Carolina.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Physician: 1A-25, Spinal Cord Stimulation.

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.

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

CPT Code	Description
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

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

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 quality of life (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 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 DRGS 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 DRGS 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 28 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 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 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 1 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 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 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 2021a 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). Neuro-modulation 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).

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 October4, 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 October4, 2023)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2024	**Applicable Codes** • Removed HCPCS codes C1767, C1778, C1816, C1820, C1822, C1823, C1883, and C1897 • Revised description for CPT codes 63685 and 63688 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CSNCT0567.06

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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