

Implanted Electrical Stimulator for Spinal Cord

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Coverage Rationale

Implanted electrical spinal cord stimulators, including high-frequency spinal cord stimulators and burst spinal cord stimulators are proven and medically necessary for treating the following indications:

- Complex regional pain syndrome (CRPS)
- Diabetic Neuropathy
- Failed back surgery syndrome

Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating the following indication:

- Refractory angina pectoris

For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Spinal Cord Stimulator (SCS) Insertion.

Click [here](#) to view the InterQual® criteria.

Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) when used according to FDA guidelines.

Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications 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.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
Implanted Electrical Stimulator for Spinal Cord	
63685 63688 L8679 L8680 L8682 L8685 L8686 L8687 L8688	<p>Medical notes documenting the following, when applicable:</p> <ul style="list-style-type: none"> ● Specific device to be implanted including all documentation <ul style="list-style-type: none"> ○ Dorsal root ganglion (DRG) stimulation <ul style="list-style-type: none"> ▪ Lead placement location <ul style="list-style-type: none"> ○ Thoracic ○ Lumbar ▪ Side <ul style="list-style-type: none"> ○ Right ○ Left ○ Dorsal column stimulator, including high-frequency dorsal column stimulators (also known as BurstDR spinal cord stimulators) <ul style="list-style-type: none"> ▪ Lead placement location <ul style="list-style-type: none"> ○ Thoracic ○ Lumbar ● Indicate if this request is for a trial or permanent placement <ul style="list-style-type: none"> ○ For permanent placement, include documentation of at least 50% pain relief with temporary implant ● Operative notes from the spinal cord stimulatory trial ● Clinical notes including: <ul style="list-style-type: none"> ○ Condition requiring procedure <ul style="list-style-type: none"> ▪ Lumbar postlaminectomy syndrome (or failed back surgery syndrome) ▪ Complex regional pain syndrome ▪ Critical limb ischemia ○ Physical examination ○ Treatments tried and failed including: <ul style="list-style-type: none"> ▪ Spine surgery ▪ Physical therapy ▪ Medications ▪ Injections ● Documentation of psychological evaluation ● Physician Plan of Care <p>For Revision or Removal</p> <p>Medical notes documenting the following, when applicable:</p> <ul style="list-style-type: none"> ● Specific device to be implanted including all documentation ● Physician evaluation ● For revision, include documentation of pain relief with prior implant ● Documentation that device has failed and cannot be repaired or is causing significant complication (e.g., skin breakdown, severe pain) ● Clinical notes including: <ul style="list-style-type: none"> ○ Condition requiring procedure ○ Physical examination ● Physician Plan of Care

*For code descriptions, see the [Applicable Codes](#) section.

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 the member specific benefit plan document 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

Clinical Evidence

Diabetic Neuropathy

A 2021 Hayes report on spinal cord stimulation 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.

Henson et al. (2021) performed a systematic review to examine the evidence and outcomes related to spinal cord stimulation for painful diabetic peripheral neuropathy. 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 quality of life 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 quality of life in patients who received spinal cord stimulation 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 spinal cord stimulation for painful diabetic neuropathy. 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 randomized controlled trials (RCTs) to assess the effectiveness of spinal cord stimulation (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 quality of life assessed as EQ-5D utility score and visual analogue scale. 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 quality of life in patients 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 conventional medical management (CMM) with 10-kHz SCS plus CMM for patients with refractory painful diabetic neuropathy (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 ($\geq 50\%$ 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 quality of life sustained over 6 months demonstrates 10-kHz SCS can safely and effectively treat patients with refractory PDN. Patients with painful diabetic neuropathy with inadequate pain relief despite best available medical treatments should be considered for 10-kHz spinal cord stimulation.

A multi-center retrospective analysis of data extracted from a commercial real-world database of patients with diabetic neuropathy 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.

Dorsal Root Ganglion (DRG) Stimulation

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, 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 dorsal root ganglion neurostimulation for the treatment of refractory, focal pain in the pelvis and lower extremities. The primary outcome was $\geq 50\%$ pain relief. Secondary outcomes were physical function, mood, quality of life, opioid usage, and complications. One randomized controlled trial, four prospective cohort studies, and eight case series were included in the review. The randomized controlled trial reported $\geq 50\%$ pain relief in 74% of patients with dorsal root ganglion neurostimulation vs. 51% of patients who experienced at least 50% relief with spinal cord stimulation 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, quality of life, opioid usage, and health care utilization, though a lack of available quantitative data limited further statistical analysis. The only randomized controlled trial reported a higher rate of adverse events than that seen with traditional neurostimulation. The authors concluded that low-quality evidence supported dorsal root ganglion neurostimulation as a more effective treatment than traditional neurostimulation for pain and dysfunction associated with complex regional pain syndrome or causalgia. Very low-quality evidence supported dorsal root ganglion 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.

A 2021 ECRI clinical evidence assessment focused on Proclaim DRG Neurostimulation System's safety and effectiveness for treating complex regional pain syndrome (CRPS). The report included 1 randomized controlled trial (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 PNI.

Kretschmar et al. (2021) conducted a retrospective chart review of patients who underwent DRG stimulation for the treatment of chronic neuropathic pain after peripheral nerve injury (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 $\geq 50\%$ pain relief) was 85%, and 23 patients received a permanent stimulator. Thirty-six-month outcome data was only available for 21 patients. Pain, quality of life, 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 quality of life. 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.

Mekharil 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, quality of life, 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.

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 $\geq 50\%$ 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.

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 $71.4 \pm 5.6\%$, 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.

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.

Totally 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. See the following website for more information (use product code LGW): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. (Accessed May 12, 2021)

There are several devices used for DRG stimulation. See the following website for more information and search by product code PMP: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. (Accessed December 8, 2021)

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Policy History/Revision Information

Date	Summary of Changes
03/01/2022	<p>Coverage Rationale</p> <ul style="list-style-type: none"> ● Removed language indicating implanted electrical spinal cord stimulators are unproven and not medically necessary for treating diabetic neuropathy ● Added language to indicate: <ul style="list-style-type: none"> ○ Implanted electrical spinal cord stimulators, including high-frequency spinal cord stimulators and burst spinal cord stimulators, are proven and medically necessary for treating diabetic neuropathy ○ Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) when used according to FDA guidelines ○ Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications [other than refractory complex regional pain syndrome (CRPS I, CPRS II)] due to insufficient evidence of efficacy ● Removed reference link to the Medical Policy titled <i>Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation</i> for dorsal root ganglion (DRG) stimulation <p>Supporting Information</p> <ul style="list-style-type: none"> ● Added <i>Clinical Evidence</i> and <i>Reference</i> sections ● Updated <i>FDA</i> section to reflect the most current information ● Archived previous policy version 2021T0567R

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.