Implanted Electrical Stimulator for Spinal Cord

Policy Number: CS061.V
Effective Date: July 1, 2022

Instructions for Use

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Commercial Policy

- Implanted Electrical Stimulator for Spinal Cord

Medicare Advantage Coverage Summary

- Electrical and Spinal Cord Stimulators

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Implanted Electrical Stimulator for Spinal Cord (for Indiana Only)
Kentucky	Implanted Electrical Stimulator for Spinal Cord (for Kentucky Only)
Louisiana	Implanted Electrical Stimulator for Spinal Cord (for Louisiana Only)
Mississippi	Implanted Electrical Stimulator for Spinal Cord (for Mississippi Only)
Nebraska	Implanted Electrical Stimulator for Spinal Cord (for Nebraska Only)
New Jersey	Implanted Electrical Stimulator for Spinal Cord (for New Jersey Only)
North Carolina	Implanted Electrical Stimulator for Spinal Cord (for North Carolina Only)
Pennsylvania	Implanted Electrical Stimulator for Spinal Cord (for Pennsylvania Only)
Tennessee	Implanted Electrical Stimulator for Spinal Cord (for Tennessee Only)

Coverage Rationale

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

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

Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris due to insufficient evidence of efficacy.

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

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

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

Click here to view the InterQual® criteria.

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

Applicable Codes

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

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

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HCPCS Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, 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

HCPCS Code	Description
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

Painful 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 (≥ 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.

Refractory Angina Pectoris

A single center prospective observational study was performed by Vervaat et al. (2020) to show the effects of spinal cord stimulation (SCS) on the severity of angina complaints and quality of life. Eighty-seven patients with refractory angina pectoris (RAP) received SCS. Ninety-two percent had angina pectoris CCS class III or IV. Ischemia was proven by MIBI-SPECT in 69%. The Seattle Angina Questionnaire (SAQ) and RAND 36-Item Health Survey (RAND-36) were completed at baseline, prior to implantation, and 1 year post-implantation. After 1 year of follow-up there was a decrease in the frequency of angina pectoris attacks from more than 4 times a day to 1-2 times a week ($p < 0.001$). The SAQ showed improvement in four of the five dimensions: physical limitation ($p < 0.001$), angina frequency ($p < 0.001$), angina stability ($p < 0.001$) and quality of life ($p < 0.001$). The improvement in satisfaction with treatment was not statistically significant ($p = 0.55$). The RAND-36 showed improvement in all nine dimensions: physical functioning ($p = 0.001$), role/physical ($p < 0.001$), social functioning ($p = 0.03$), role/emotional ($p < 0.05$), bodily pain ($p < 0.001$), general health ($p < 0.001$), vitality ($p < 0.001$), mental health ($p = 0.02$) and health change ($p < 0.001$). Secondary findings of this study were a reduction in the use of short-acting NTG use from 1-3 times a day to less than once a week, low cardiovascular mortality (1.1%) and low all-cause mortality (3.4%). The authors concluded that the study showed a significant improvement in quality of life 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 spinal cord stimulation (SCS) in the treatment of refractory angina pectoris (RAP). Five meta-analyses were performed examining the changes in Canadian Cardiovascular Society classes, exercise time, Visual Analog Scale (VAS) scores of pain, Seattle Angina Questionnaire, and nitroglycerin use in RAP patients after SCS therapy. Twelve randomized controlled trials involving 476 RAP patients were included. The results identified reduction in the angina frequency and nitroglycerin consumption in the SCS group. Compared with the control group, SCS showed benefit on increasing exercise time and treatment satisfaction with decreased VAS scores of pain and disease perception. The result did not reach the significance level in terms of physical limitation ($p = 0.39$) or angina stability ($p = 0.50$). The authors concluded that SCS relieves the symptoms of angina pectoris without increasing the nitroglycerin consumption to some extent. Future larger outcome studies for finding the appropriate intensity of stimulation are needed.

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

Tsigaridas et al. (2015) conducted a systematic review of RCTs to investigate the effectiveness of SCS as a treatment for refractory angina. Nine RCTs were categorized into two groups: RCTs comparing SCS either with optimal medical treatment or inactive mode or low stimulation SCS; and those comparing SCS with alternative therapeutic interventions. Follow-up was 1-6 months in most studies, showing no major complications. Two studies reported a neutral effect regarding mortality. The most

recent, multi-center RCT reported no significant difference compared to the control group. The authors concluded that RCTs investigating the efficacy of SCS were small and they demonstrated a small effect in angina improvement. Larger, well-designed, multicenter RCTs are needed with longer follow-up.

Dorsal Root Ganglion (DRG) Stimulation

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

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.

Kretzschmar 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 ≥ 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 (This study is included in the Hayes 2021a report).

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

Huygen 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 quality of life 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) of dorsal root ganglion (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 diabetic neuropathy, 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 neuro-modulation 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 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 2021a report).

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

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. Refer to 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. 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 December 8, 2021)

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Policy History/Revision Information

Date	Summary of Changes

07/01/2022	**Coverage Rationale**
	• Replaced language indicating:
	  ○ "Implanted electrical spinal cord stimulators, *including high-frequency spinal cord stimulators and burst spinal cord stimulators*, are proven and medically necessary for treating the [listed] indications" with "implanted electrical spinal cord stimulators are proven and medically necessary for treating the [listed] indications *in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions*"
	  ○ "Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris" with "implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris *due to insufficient evidence of efficacy*"
	  ○ "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 U.S. Food and Drug Administration (FDA) *guidelines*" with "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*"
	• Revised list of indications for which implanted electrical spinal cord stimulators are proven and medically necessary; replaced "diabetic neuropathy" with "*painful lower limb* diabetic neuropathy"
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS061.U

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