Spinal Cord Stimulators for Chronic Pain

Policy Number: MMP368.11
Last Committee Approval Date: May 8, 2024
Effective Date: June 1, 2024

➲ Instructions for Use

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Coverage Rationale

Overview

Spinal cord stimulation (SCS), also referred to as dorsal column stimulation, uses electrodes implanted into the epidural space and is connected to a pulse generator to manage pain. Implantation of a spinal cord stimulator has two phases. First, a trial of SCS is performed prior to permanent implantation using a temporary electrical stimulator connected to an external pulse generator. The second phase consists of a permanent implantation of the SCS, which requires percutaneous insertion of an electrode into the epidural space under fluoroscopy. The tip of the electrode is advanced to the appropriate level in the epidural space behind the dorsal column, and the other end of the electrode is connected through a subcutaneous tunnel to an internal pulse generator implanted under the skin in the abdominal wall or low back.

Centers for Medicare & Medicaid (CMS) National Coverage Determinations (NCDs)

For coverage guidelines, refer to the NCD for Electrical Nerve Stimulators (160.7).

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Spinal Cord Stimulators for Chronic Pain.

For states/territories with no LCDs/LCAs, for uses of spinal cord stimulators for chronic intractable pain not specifically addressed by the NCD for Electrical Nerve Stimulators (160.7), refer to the following for coverage guidelines:

The implantation of spinal cord stimulators (SCS) may be covered as therapies for the relief of chronic intractable pain. SCS is best suited for neuropathic pain but may have some limited value in other types of nociceptive severe, intractable pain. Therapy consists of a short trial with a percutaneous implantation of neurostimulator electrode(s) in the epidural space for assessing a patient's suitability for ongoing treatment with a permanent surgically implanted nerve stimulator. Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation. In situations where the spinal cord stimulator has been working well but is in need of replacement for battery change, malfunction, or end of stimulator life, a new trial is not needed to replace the stimulator.

Selection of patients for implantation of spinal cord stimulators is critical to the success of this therapy. SCS therapy should be considered as a late option after more conservative attempts such as medications, physical therapy, psychological therapy, or other modalities have been tried.

Patients must have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. Such screening must include psychological, as well as physical evaluation.

It is preferable that physicians performing the SCS trial will also perform the permanent implant. If the physician implanting the trial neurostimulator does not or cannot implant the permanent neurostimulator, the patient should be informed of this in writing and given the name of the referral surgeon who will implant the permanent neurostimulator(s).

It is expected that accurate patient selection will lead to most patients going on to receive permanent implants following a trial. Permanent implantation of SCS is medically necessary when, in addition to the requirements above, the following conditions are met:

- A trial achieved at least a 50% reduction of target pain or 50% reduction of analgesic medications; and
- Some element of functional improvement was achieved

Note: Patients with reflex sympathetic dystrophy may show lower levels of improvement since it takes longer periods for improvement than the typical 1-2 week trial.

All trials which proceed to permanent implant must have adequate documentation in the chart to support that decision.

If a trial fails, a repeat trial is not appropriate unless there are extenuating circumstances that lead to trial failure.

Dorsal root ganglion (DRG) stimulators may be covered when coverage criteria for spinal cord stimulation are met.

UnitedHealthcare uses the criteria above to supplement the NCD criteria related to demonstration of pain relief with a temporarily implanted electrode in order to determine when implantation of a spinal cord stimulator for chronic intractable pain is reasonable and necessary. UnitedHealthcare uses the criteria noted above in order to ensure consistency in reviewing the conditions to be met for coverage of spinal cord stimulator implantation for chronic intractable pain, as well as reviewing when such services may be medically necessary. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure implantation of a spinal cord stimulator for chronic intractable pain is not incorrectly denied when medically appropriate for a particular patient nor incorrectly approved when not reasonable and necessary for a patient. Specifically, limiting incorrect approvals of spinal cord stimulators limits the risks associated with inappropriate implantation of a permanent neurostimulator including the risk of unnecessary complications such as infection, hemorrhage, migration of electrode, wire breakage, therapy failure, device failure, and need for reposition. In addition, there is a surgical risk of device placement in the epidural space, sometimes requiring a laminectomy for proper placement. The importance of initial trial stimulation via a temporary stimulator should be stressed as a key decision point. The potential clinical harms of using these criteria may include inappropriately denying spinal cord stimulator implantation, which may result in inadequate pain reduction, lack of improvement in daily functioning, adverse effects from medications over time, and poor long-term outcomes. Patients inappropriately denied spinal cord stimulators may then receive health care services that provide minimal benefit or potentially cause harm, which can lead to the development of opioid use disorder or unnecessary spinal fusion surgery and related complications. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials based on the primary and secondary end points from clinical studies shown in this policy including ≥ 50% pain relief, functional improvement, and reported reductions in opioid use. The added criteria will provide numerous clinical benefits in helping avoid unnecessary complications from inappropriate implantations. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria.

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 guideline 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

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

Diagnosis Codes
Spinal Cord Stimulators for Chronic Pain: Diagnosis Code List

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	Article	Contractor Type	Contractor Name
Spinal Cord Stimulators for Chronic Pain				
Electrical Nerve Stimulators (160.7)	L35136 Spinal Cord Stimulators for Chronic Pain	A57791 Billing and Coding: Spinal Cord Stimulators for Chronic Pain	Part A and B MAC	Noridian
	L36204 Spinal Cord Stimulators for Chronic Pain	A57792 Billing and Coding: Spinal Cord Stimulators for Chronic Pain	Part A and B MAC	Noridian
	L37632 Spinal Cord Stimulators for Chronic Pain	A56876 Billing and Coding: Spinal Cord Stimulators for Chronic Pain	Part A and B MAC	Palmetto
	L35450 Spinal Cord Stimulation (Dorsal Column Stimulation) **Retired 07/13/2023**	A57023 Billing and Coding: Spinal Cord Stimulation (Dorsal Column Stimulation) **Retired 07/13/2023**	Part A and B MAC	Novitas
	L36035 Spinal Cord Stimulation for Chronic Pain **Retired 07/13/2023**	A57709 Billing and Coding: Spinal Cord Stimulation for Chronic Pain **Retired 07/13/2023**	Part A and B MAC	First Coast

Medicare Administrative Contractor (MAC) with Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, DC
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
*__Note__: Wisconsin Physicians Service Insurance Corporation Contract Number 05901 - applies only to WPS Legacy Mutual of Omaha MAC A Providers	

Clinical Evidence

Spinal Cord Stimulation (Traditional and High-Frequency)

This clinical evidence review focuses on spinal cord nerve stimulators and whether the current available evidence is sufficient to draw conclusions about improved health outcomes for the Medicare population. Based on the clinical evidence reviewed from systematic reviews, meta-analyses, and randomized controlled trials, ideal patient outcomes include equal to or greater than 50% pain reduction, improved functional ability, and improved quality of life.

Petersen et al. (2023) conducted a prospective, multicenter, randomized, open-label clinical trial (SENZA-PDN study) at 18 centers throughout the United States to assess the long-term efficacy of high-frequency (10 kHz) spinal cord stimulation (SCS) for treating patients with at least 12 months of refractory painful diabetic neuropathy (PDN) symptoms. The mean age of the study participants was 60.8 years, and 63% were male. The trial compared conventional medical management (CMM) alone (n= 103) to 10 kHz SCS plus CMM (n= 113) for a total of 216 patients with refractory PDN, with optional crossover at six (6) months if specific criteria were met (i.e., less than 50% pain relief from baseline, were dissatisfied with their treatment, and the investigator agreed that the switch was appropriate). A total of 181 patients underwent a 10 kHz SCS trial, including the original 10 kHz SCS+CMM recipients and those who received 10 kHz SCS+CMM after crossing over from CMM alone. The authors report that, of the 181 patients who underwent a 10kHz SCS trial, 171 (94.5%) had a successful trial, 154 underwent permanent implantation, and 142 completed 24 months of follow-up. The authors reported no stimulation-related neurological deficits and no devices explanted due to lack of efficacy. The authors also reported that, of the 154 permanently implanted participants, seven (4.5%) experienced a study-related serious adverse event (SAE), and eight (5.2%) had a procedure-related infection, with three of the infections resolving with standard treatment. The authors reported that five (3.2%) SCS systems were explanted due to infection, of which four left the study and one continued participation after reimplantation. At 24-month post-implantation, the authors reported that 10 kHz SCS reduced pain by a mean of 79.9% among all implanted participants compared to baseline, with 90.1% of participants experiencing ≥50% pain relief, and 65.7% had neurological improvement. There were no patients with increased pain relative to baseline. The authors concluded that the safety results support that diabetic patients do not have additional risk of complications with SCS. Limitations of the study included lack of blinding of participants and study personnel, leading to a risk of biased outcomes and a possible placebo effect. Also, investigators were not blinded to the treatment allocation when evaluating the neurological outcomes. In conclusion, high-frequency (10 kHz) spinal cord stimulation treatment provides durable pain relief in patients with refractory lower limb PDN pain and improved health-related quality of life (HRQoL) and sleep at 24 months post-implantation.

Deer et al. (2023) conducted a multicentered, prospective, randomized controlled trial [Dorsal Spinal Cord Stimulation vs Medical Management for the Treatment of Low Back Pain (DISTINCT) study] 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. 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 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.

Mons et al. (2023) performed a prospective, single-arm, single-center, post-market, pilot study 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.

Ghorayeb et al. (2023) conducted a systematic review to investigate the clinical use and effectiveness of dorsal root ganglion stimulation (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.

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 (SR) 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).

Moman et al. (2022) led a systematic review and pooled analysis to decide the overall incidence of dorsal root ganglion stimulation (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, seven 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 DRGS 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 that 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.

Mol et al. (2022) conducted an assessment of a multicenter, crossover, nonblind randomized controlled study comparing DRG stimulation 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 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.

Nagpal et al. (2021) conducted a systematic review 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, quality of life (QoL), opioid usage, and complications. One randomized controlled trial, four prospective cohort studies, and eight case series were included in the review. The RCT reported ≥ 50% pain relief in 74% of patients with DRG neurostimulation vs. 51% of patients who experienced at least 50% relief with SCS at 3 months. Cohort data success rates ranged from 43% to 83% at ≤ 6 months and 27% to 100% at > 6 months. Significant improvements were also reported in the secondary outcomes assessed, including mood, QoL, opioid usage, and health care utilization, though a lack of available quantitative data limited further statistical analysis. The only RCT reported a higher rate of adverse events (AEs) than that seen with traditional neurostimulation. The authors concluded that low-quality evidence supported DRG neurostimulation as a more effective treatment than traditional neurostimulation for pain and dysfunction associated with complex regional pain syndrome (CRPS) or causalgia. Very low-quality evidence supported DRG neurostimulation for the treatment of chronic pelvic pain, chronic neuropathic groin pain, phantom limb pain, chronic neuropathic pain of the trunk and/or limbs, and diabetic neuropathy (DPN).

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

Eckermann et al. (2021) performed a systematic review to identify studies reporting outcomes for SCS in chronic back pain patients (with or without secondary radicular leg pain) without prior surgery. The primary outcomes measured were the magnitude of change in pain from baseline to follow-up, the proportion of subjects achieving a 50% reduction in pain, and AEs related to the device or procedure. Outcome measures related to improvements in QoL, disability, function, and changes in medication use were also evaluated. A total of ten studies were included (including a total of 357 patients). Final follow-up periods across all studies ranged from 12 to 36 months. In a majority of studies, reductions in pain were observed as early as 3 months after treatment, with reductions in pain also evidenced at 6, 9, 12, 24, and 36 months postintervention. The authors reported that the studies demonstrated favorable outcomes in terms of pain reduction and functional improvement following SCS therapy. Improvements also occurred in quality-of-life scores; however, not all studies reported statistically significant findings. The studies reported that SCS resulted in high patient satisfaction, reductions in opioid use, and an acceptable safety profile, although these data were more limited. The authors concluded that SCS is a promising, safe, minimally invasive, and reversible alternative option for managing chronic back pain in patients who have not undergone spinal surgery. The studies were predominantly observational with relatively small sample sizes, and many studies did not have a comparison or control group.

Baranidharan et al. (2021) performed a prospective, single center, open label trial to explore the use of SCS in patients with associated allodynia and hyperalgesia. Twenty-one individuals with back pain and hyperalgesia or allodynia who had not had prior spinal surgery underwent a SCS trial followed by full implantation. Patients attended follow-up visits after 6 and 12 months of SCS. Repeated measure analysis of variance (ANOVA)/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).
Deer et al. (2020) conducted a systematic literature review of randomized controlled studies (RCTs) on spinal cord stimulation (SCS) for patients with at least 12 months of chronic, intractable limb or back pain or complex regional pain syndrome (CRPS). A total of six studies were included in the review. Five of the trials were for spine and/or limb RCTs, and all were ranked high quality based on study design and outcomes. Four of the five RCTs in this review had industry support but had high quality scores for perceived avoidance of bias using the Cochrane scoring methodology. Several key points identified by the authors include: SCS is more effective for pain relief than reoperation or conventional medical management (CMM) alone for patients with failed back surgery syndrome (FBSS), and SCS has proven efficacy for chronic pain syndromes. The sixth study in this review was on a randomized trial evaluating CRPS that had US Preventive Services Task Force (USPSTF) Level I evidence based on the rigorous qualifications for consideration. Fifty-four subjects in that study were randomized 2:1 (patients allocated to combined treatment with physical therapy (PT) and SCS or PT alone), which prevented patient blinding. The authors reported 36 patients trialed SCS with 24 having successful trials and proceeded to permanent device implantation. The authors also reported that at the five-year follow-up, ninety-five percent of the SCS-treated patients indicated that they would undergo SCS again for the same result. Health-related quality of life improved significantly in the SCS-treated group at six and 24 months but equalized at five years. The authors stated that the subjects with SCS implants had improved range of motion in the limbs compared with the PT-alone cohort. The authors indicated that there was no standard method for defining adverse events or complications in a longitudinal view of the studies included in this review. Most of the studies were limited by lack of subject/investigator blinding, and some had industry funding as another source of bias. The authors concluded that SCS is safe and effective for chronic spine pain, FBSS, neuropathic pain, and CRPS.

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 implantable pulse generator (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.

Vuka et al. (2019) conducted 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. 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, diabetic peripheral neuropathy (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 serious adverse event (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.

Amirdelfan et al. (2018) conducted a prospective, multicenter, RCT (SENZA-RCT). 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. Quality of life (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).

Scalone et al. (2018) conducted a multi-center prospective study assessing the health-related quality of life (HRQoL) in patients with failed back surgery syndrome (FBSS), the relationship between pain, physical disability, and how these health outcomes change from a spinal cord stimulation (SCS) intervention over a 24-month period. This study used real-world context to assess patient trends post SCS intervention to establish instruments for use in clinical practice to optimize treatment benefits for patients with FBSS. The study took place across nine specialty centers (six specialized in pain and three in neurosurgery) across Italy for a total of eighty participants with a mean age of 58 years, and 40% were male. During the study, each patient underwent a percutaneous lead implantation and were observed during a 15-day trial period. Patients with a positive response to the trial (defined as at least 50% pain reduction and 80% overlap of pain with induced stimulation) were implanted with a pulse generator and followed for up to two years. Data collection occurred during the pre-SCS period (12 months prior to enrollment) and at every 6-month follow-up visit for two years after implantation during the post-SCS period. Each patient's pain intensity was assessed using the Numerical Rating Scale (NRS) to rate the average and maximum perceived pain in the previous 12 months (at enrollment) or in the previous six months (during the follow-up window). Two generic questionnaires that were used in other recent studies were also conducted in this study to assess physical and psychological components of health, as they allow comparing health within and between different clinical conditions and with the general population. The authors reported that patient level of pain perception on average was high with a mean level of 7.6 and maximum of 9.2 using the NRS. The authors also reported that 65% of the patients experienced extreme pain or discomfort on the Oswestry Disability Index (ODI) and that 47 to 70% of patients had maximum levels of disability in standing, travelling, lifting, sexual function, and social life. The authors also reported that 21-32% of the patients experienced serious problems with sleeping, sitting, and personal care and reported that the total ODI score was high (mean value of 61.6). Additionally, the authors reported that the Physical Component Summary (PCS) that assessed physical functioning had an overall score of 43.3% for patients' inability to do usual activities. The authors concluded that study subjects had a significantly impaired HRQoL compared to the general population in Italy of the same age, sex, and education level; patients with the higher pain levels (NRS) and of disability (ODI) scores had worse levels of HRQoL. Scalone et al identified that six months after SCS implantation, "an improvement of health was found in every domain of every instrument used." During the follow-up period, the authors determined that pain and disability scores decreased as HRQoL increased significantly within the first six months of treatment with SCS and remained stable six months post-implantation. This real-world study indicates that pre- and post-implantation assessment of pain, functional disability, and health-related quality of life are clinically relevant for patients being treated with spinal cord stimulation for failed back surgery syndrome refractory to conventional medical management. Study limitations include no control group and small sample size.

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).

de Vos et al. (2014) conducted a multi-center, randomized trial to assess the effectiveness of spinal cord stimulation (SCS) in 60 patients with painful diabetic peripheral neuropathy (PDPN) in the lower extremities for at least one year. Patients were randomized 2:1 to receive either conventional medical therapy alone (control) or in combination with spinal cord stimulation (SCS). Participants had exhausted all conventional treatment but still had an average pain rating of 50 on the visual analog scale (VAS). For all patients in both groups, conventional treatments were allowed at any time during the study. In the treatment group, one electrode lead (Octrode or S8 Lamitrode™; St Jude Medical, Plano, TX) was implanted in the epidural space and positioned where the patient reported optimal overlap between paresthesia and the painful area. Those with a successful 7-day trial showing at least 50% improvement in pain intensity proceeded with SCS implantation. A pulse generator (EonC, Eon, or Eon Mini; St Jude Medical) was implanted subcutaneously in either the anterior abdominal wall or the upper buttock and connected to the electrode lead that was also used during trial stimulation. Thirty-six patients in the SCS group and 18 patients in the control group were followed for six months. de Vos et al identified that 26 patients in the SCS group experienced more than 50% pain reduction compared to baseline versus three patients in the control group. The authors reported adverse events related to SCS implantation include pain due to the implanted pulse generator (2), electrode lead migration (1), infection (1), and coagulopathy (1). The authors concluded that the findings suggest SCS in combination with conventional medical therapy significantly reduces pain and improves quality of life in patients with refractory PDPN in the lower extremities. This study is limited by its open label design, small sample size, lack of blinding, and potential bias created by offering patients in the control group a crossover to SCS after six months.

Clinical Practice Guidelines

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) 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 April 22, 2024)

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 April 22, 2024)

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Policy History/Revision Information

Date	Summary of Changes

06/01/2024	**Template Update**
	• Reformatted and reorganized policy; transferred content to new template
	• Changed policy type classification from "Policy Guideline" to "Medical Policy"
	• Added *Clinical Evidence, FDA,* and *References* sections
	• Updated *Instructions for Use*
	Related Policies
	• Added reference link to the UnitedHealthcare Commercial Medical Policy titled *Implanted Electrical Stimulator for Spinal Cord*
	Coverage Rationale
	Overview
	• Added language to indicate:
	  ○ Spinal cord stimulation (SCS), also referred to as dorsal column stimulation, uses electrodes implanted into the epidural space and is connected to a pulse generator to manage pain
	  ○ Implantation of a spinal cord stimulator has two phases
	  ▪ First, a trial of SCS is performed prior to permanent implantation using a temporary electrical stimulator connected to an external pulse generator
	  ▪ The second phase consists of a permanent implantation of the SCS, which requires percutaneous insertion of an electrode into the epidural space under fluoroscopy
	  – The tip of the electrode is advanced to the appropriate level in the epidural space behind the dorsal column, and the other end of the electrode is connected through a subcutaneous tunnel to an internal pulse generator implanted under the skin in the abdominal wall or low back
	Centers for Medicare & Medicaid (CMS) National Coverage Determinations (NCDs)
	• Added instruction to refer to the NCD for *Electrical Nerve Stimulators (NCD 160.7)* for coverage guidelines
	CMS Local Coverage Determinations (LCDs) and Articles
	• Revised language to indicate:
	  ○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *CMS Related Documents* section of the policy]
	  ○ For states/territories with no LCDs/LCAs, for uses of spinal cord stimulators for chronic intractable pain not specifically addressed by the NCD for *Electrical Nerve Stimulators (NCD 160.7)*, refer to the following for coverage guidelines:
	  ▪ The implantation of spinal cord stimulators (SCS) may be covered as therapies for the relief of chronic intractable pain
	  ▪ SCS is best suited for neuropathic pain but may have some limited value in other types of nociceptive severe, intractable pain
	  ▪ Therapy consists of a short trial with a percutaneous implantation of neurostimulator electrode(s) in the epidural space for assessing a patient's suitability for ongoing treatment with a permanent surgically implanted nerve stimulator
	  ▪ Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation

Date	Summary of Changes
	▪ In situations where the spinal cord stimulator has been working well but is in need of replacement for battery change, malfunction or end of stimulator life, a new trial is not needed to replace the stimulator ▪ Selection of patients for implantation of spinal cord stimulators is critical to the success of this therapy ▪ SCS therapy should be considered as a late option after more conservative attempts such as medications, physical therapy, psychological therapy, or other modalities have been tried ▪ Patients must have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation; such screening must include psychological, as well as physical evaluation ▪ It is preferable that physicians performing the SCS trial will also perform the permanent implant; if the physician implanting the trial neurostimulator does not or cannot implant the permanent neurostimulator, the patient should be informed of this in writing and given the name of the referral surgeon who will implant the permanent neurostimulator(s) ▪ It is expected that accurate patient selection will lead to most patients going on to receive permanent implants following a trial ▪ Permanent implantation of SCS is medically necessary when, in addition to the requirements above, the following conditions are met: – A trial achieved at least a 50% reduction of target pain or 50% reduction of analgesic medications; and – Some element of functional improvement was achieved ▪ Patients with reflex sympathetic dystrophy may show lower levels of improvement since it takes longer periods for improvement than the typical 1–2-week trial ▪ All trials which proceed to permanent implant must have adequate documentation in the chart to support that decision ▪ If a trial fails, a repeat trial is not appropriate unless there are extenuating circumstances that lead to trial failure ▪ Dorsal root ganglion (DRG) stimulators may be covered when coverage criteria for spinal cord stimulation are met ○ UnitedHealthcare uses the criteria above: ▪ To supplement the NCD criteria related to demonstration of pain relief with a temporarily implanted electrode in order to determine when implantation of a spinal cord stimulator for chronic intractable pain is reasonable and necessary ▪ In order to ensure consistency in reviewing the conditions to be met for coverage of spinal cord stimulator implantation for chronic intractable pain, as well as reviewing when such services may be medically necessary ▪ Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure implantation of a spinal cord stimulator for chronic intractable pain is not incorrectly denied when medically appropriate for a particular patient nor incorrectly approved when not reasonable and necessary for a patient; specifically, limiting incorrect approvals of spinal cord stimulators limits the risks associated with inappropriate implantation of a permanent neurostimulator including the risk of unnecessary complications such as infection, hemorrhage, migration of electrode, wire breakage, therapy failure, device failure, and need for reposition; in addition, there is a surgical risk of device placement in the epidural space, sometimes requiring a laminectomy for proper placement ▪ The importance of initial trial stimulation via a temporary stimulator should be stressed as a key decision point ○ The potential clinical harms of using these criteria may include inappropriately denying spinal cord stimulator implantation, which may result in inadequate pain reduction, lack of improvement in daily functioning, adverse effects from medications over time, and poor long-term outcomes ▪ Patients inappropriately denied spinal cord stimulators may then receive health care services that provide minimal benefit or potentially cause harm, which can lead to the development of opioid use disorder or unnecessary spinal fusion surgery and related complications

Date	Summary of Changes
	○ The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials based on the primary and secondary end points from clinical studies shown in this policy including ≥ 50% pain relief, functional improvement, and reported reductions in opioid use ▪ The added criteria will provide numerous clinical benefits in helping avoid unnecessary complications from inappropriate implantations; in addition, use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria **Applicable Codes** • Removed CPT codes 63661, 63662, 63663, 63664, and 63688 **CMS Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information • Added list of applicable *Medicare Administrative Contractors (MACs) with Corresponding States/Territories* **Supporting Information** • Archived previous policy version MPG368.10

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

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For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.