MEDICAL POLICY

POLICY TITLE	SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION
POLICY NUMBER	MP 1.069

Effective Date:	9/1/2023

I. POLICY

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Implantation of a temporary trial spinal cord stimulation (SCS) device may be considered **medically necessary** to predict whether a spinal cord stimulator will induce significant pain relief with chronic pain when **ALL** of the following criteria are met:

- The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature (i.e., resulting from actual damage to the peripheral nerves). Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury);
- No serious untreated drug habituation exists;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Spinal cord stimulation with standard or high-frequency stimulation may be considered **medically necessary** for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies when **ALL** the following criteria are met:

- The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature (i.e., resulting from actual damage to the peripheral nerves). Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury);
- No serious untreated drug habituation exists;

- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Dorsal root ganglion neurostimulation may be considered **medically necessary** for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies when **ALL** the following criteria are met:

- The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury).
- No serious untreated drug habituation exists;
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Spinal cord stimulation is considered **investigational** in all other situations, including but not limited to treatment of critical limb ischemia to forestall amputation, treatment of refractory angina pectoris, heart failure, and cancer-related pain. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

"Burst" neurostimulation is an alternate programming of a standard spinal cord stimulation device. A clinician programmer application is used to configure a standard spinal cord stimulation device to provide stimulation in "bursts" rather than at a constant ("tonic") rate.

Cross-References:

MP 1.042 Deep Brain Stimulation
MP 6.020 Transcutaneous Electrical Nerve Stimulation (TENS)
MP 6.045 Sympathetic Therapy for the Treatment of Pain
MP 6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP 6.047 Interferential Current Stimulation
MP 6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP 6.049 H-Wave Electrical Stimulation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Chronic Pain

Spinal cord stimulation (SCS) has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome (i.e., chronic reflex sympathetic dystrophy). There has also been interest in SCS as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest pain.

For those patients with neuropathic pain who are unable to achieve an acceptable quality of life, neurostimulation is a treatment option.

Spinal Cord Stimulation

SCS (also called dorsal column stimulation) involves the use of low-level epidural electrical stimulation of the spinal cord dorsal columns. The neurophysiology of pain relief after SCS is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits. Electrostimulation for pain therapy emerged in the convergence of Pacemaker technology, the “Gate control” theory of pain, and pioneering clinical trials from 1950s to 1960s. According to this theory, the activation of low-threshold nonnociceptive fibers closes the gate of the nociceptive signal input through the activation of inhibitory neurons in the spinal cord to suppress pain. SCS is a form of electrotherapy by implanting electrodes into the epidural space in the spinal cord and stimulating the dorsal column to modulate neural function.

SCS devices consist of several components: (1) the lead that delivers the electrical stimulation to the spinal cord; (2) an extension wire that conducts the electrical stimulation from the power source to the lead; and (3) a power source that generates the electricity. The lead may incorporate from four to eight electrodes, with eight electrodes more commonly used for complex pain patterns. There are two basic types of power source: one type, the power source (battery), can be surgically implanted or worn externally with an antenna over the receiver; the other, a radiofrequency receiver, is implanted. Totally implantable systems are most commonly used.

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The patient's pain distribution pattern dictates at what level of the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used. For example, a lead with eight electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a 2-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful SCS may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10,000 Hz) than predicate devices, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesia's, which are a recognized effect of SCS. In 2016, the FDA approved a clinician programmer application that allows an SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesia's. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five, 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of one ms.

The incidence of adverse events related to spinal cord stimulation have been reported to occur in 30% to 40% of cases. Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration or lead failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache (estimated incidence, up to 0.3%) and neurological damage (estimated incidence, 0.25%).

Other neurostimulators target the dorsal root ganglion. Dorsal root ganglia consist of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system and play a role in neuropathic pain perception. Dorsal root ganglia are located in the epidural space between spinal nerves and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Two systems targeting the DRG have received approval or clearance from the FDA.

A retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of DRG stimulation. The MAUDE database was queried for dorsal root ganglion stimulation reports through 2017, identifying 979 episodes. Complications were predominantly device-related (47%; lead migration and lead damage), with the remaining comprised of procedural complications (28%; infection, new neurologic symptoms, and dural puncture), patient complaints (12%; site pain and unwanted stimulation), serious adverse events (2.4%), and "other" complications (4.6%). The prevalence of complications cannot be estimated using the MAUDE database; while facilities are mandated to report events, patients and health care providers may report events but are not mandated to do so.

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In September 2020, the FDA released a letter to healthcare providers reminding them to conduct a trial stimulation period before implanting a spinal cord stimulator as the agency continues to receive reports of serious adverse effects associated with these devices. Between July 27, 2016, and July 27, 2020, the FDA received 107,728 medical device reports related to spinal cord simulators intended for pain including 497 associated with patient death, 77,937 with patient injury, and 29,924 with device malfunction. The most frequently reported patient problem codes were inadequate pain relief (28.1%), pain (15.2%), unexpected therapeutic effects (10.9%), infection (7.5%), and discomfort (5.9%). Additionally, the most frequently reported device problem codes were charging problems (11.2%), impedance (10.6%), migration (7.2%), battery problem (6.4%), and premature discharge of battery (4.2%).

The FDA made the following recommendations for clinicians to consider:

- Conduct a trial stimulation as described in the device labeling to identify and confirm satisfactory pain relief before permanent implantation.
- Permanent spinal cord stimulation should only be implanted in patients who have undergone and passed a stimulation trial.
- Providers typically perform a stimulation trial on a patient for 3 to 7 days, and success is usually defined by a 50% reduction in pain symptoms. Inform patients about the risks of serious side effects and what to expect during the trial stimulation.
- Before implantation of any spinal cord stimulation, discuss the benefits and risks of the different types of implants and other treatment options, including magnetic resonance imaging (MRI) compatibility of the devices.
- Before implantation, provide patients with the manufacturer's patient labeling and any other education materials for the device that will be implanted.
- Develop an individualized programming, treatment, and follow-up plan for spinal cord stimulation therapy delivery with each patient.
- Provide each patient with the name of the device manufacturer, model, and the unique device identifier of the implant received.

Regulatory Status

Many neurostimulator devices have been approved by the FDA through the premarket approval process under FDA product code: LGW (stimulator, spinal-cord, totally implanted for pain relief), PMP (Dorsal Root Ganglion Stimulator for Pain Relief), and GZB (Stimulator, Spinal-Cord, Implanted [Pain Relief]) (Table 1).

In October 2016, the FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients with certain St. Jude spinal cord stimulation devices.

Table 1. Premarket Approval Information for Devices

Device and Manufactuer	Product Code	Original approval date	Original PMA number	Indication

Algovita SCS System Nuvectra Corporation	LGW	Nov 2015	P130028	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain.
Axium (1st generation) and Proclaim DRG (2nd generation) Neurostimulator System Abbott Medical	PMP	Feb 2016	P150004	Moderate to severe chronic intractable pain of the lower limbs in adult patients with Types I and II CRPS
Cordis Programmable Neural Stimulator Models 900a Cordis Corporation	LGW	Apr 1981[a]	P800040	Stimulator, Spinal-Cord, Totally Implanted For Pain Relief
Freedom SCS Stimwave Technologies	GZB	Aug 2016	K180981	Chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain
Genesis And Eon Family Neurostimulation (Ipg) System St. Jude Medical/ Abbott Medical	LGW	Nov 2001	P010032	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain
Itrel Totally Implantable SCS Medtronic Neuromodulation	LGW	Nov 1984	P840001	Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions: • Failed Back Syndrome (FBS) or low back syndrome or failed back • Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk • Postlaminectomy pain • Multiple back operations • Unsuccessful disk surgery • Refractory Degenerative Disk

				Disease (DDD)/herniated disk pain • Peripheral causalgia • Epidural fibrosis • Arachnoiditis or lumbar adhesive arachnoiditis • Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia • Diabetic peripheral neuropathy of the lower extremities
Precision SCS Systems Boston Scientific Corporation	LGW	Apr 2004	P030017	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, Types 1 and 2 CRPS, intractable low back pain and leg pain
Senza SCS System Nevro Corporation	LGW	May 2015	P130022	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain When programmed to include a frequency of 10 kHz: Chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy; non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery)

CRPS: Complex regional pain syndrome; PMA: premarket approval; SCS: spinal cord stimulation.
[a] Withdrawn in 2016

IV. RATIONALE

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Summary of Evidence

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard spinal cord stimulation, the evidence includes systematic reviews and randomized controlled trials (RCTs). The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Available RCTs are mixed regarding underlying diagnoses in select patient populations. However, those trials including patients with underlying neuropathic pain processes have shown a significant benefit with spinal cord stimulation. Systematic reviews have supported the use of spinal cord stimulation to treat

refractory trunk or limb pain, and patients who have failed all other treatment modalities have few options. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency spinal cord stimulation, the evidence includes a systematic review and 4 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Two RCTs that enrolled participants not previously treated with spinal cord stimulation reported clinically and statistically significant benefits associated with high-frequency spinal cord stimulation. Another RCT in patients who had chronic pain despite previous treatment with standard spinal cord stimulation found no benefit for those receiving high-frequency stimulation compared with sham-control; however, it is difficult to compare these findings with other trials of spinal cord stimulation due to the different patient populations, short treatment periods, and the crossover period effect. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion neurostimulation, the evidence includes a systematic review, an RCT, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The unblinded RCT found that patients receiving dorsal root ganglion neurostimulation had significantly higher rates of treatment success (physical functioning score and quality of life measures), at 3 and 12 months compared with those receiving standard spinal cord stimulation devices. Dorsal root ganglion neurostimulation was found to be noninferior to spinal cord stimulation in the percentage achieving >50% pain reduction, emotional functioning score, and 36-Item Short-Form Health Survey scores. Both groups experienced paresthesias but patients in the dorsal root ganglion group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the two study arms. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Critical Limb Ischemia

For individuals who have critical limb ischemia who receive spinal cord stimulation, the evidence includes systematic reviews of several small RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. In pooled analyses, spinal cord stimulation was associated with a lower risk of amputation versus control, but results were not consistently statistically significant due to differences in methodologies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Treatment-Refractory Angina Pectoris

For individuals who have treatment-refractory angina pectoris who receive spinal cord stimulation, the evidence includes systematic reviews and RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. Numerous small RCTs have evaluated spinal cord stimulation as a treatment for refractory angina. While some have reported benefits, most have not. In two recent RCTs, there was no significant benefit in the primary outcomes. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome.

Heart Failure

For individuals who have heart failure who receive spinal cord stimulation, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. An RCT (n=66) comparing spinal cord stimulation using active stimulation with sham-control in patients who had New York Heart Association functional class III heart failure and a left ventricular ejection fraction of 35% or less did not find significant differences between groups but might have been underpowered to do so. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Cancer-Related Pain

For individuals who have cancer-related pain who receive spinal cord stimulation, the evidence includes case series. The relevant outcomes are symptoms, functional outcomes, medication use, and treatment-related morbidity. No RCTs evaluating spinal cord stimulation in this population were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is

determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
C1767	C1778	C1787	C1820	C1822	C1826	C1827	C1883	C1897
L8679	L8680	L8681	L8682	L8683	L8685	L8686	L8687	L8688
L8689	63650	63655	63661	63662	63663	63664	63685	63688
95970	95971	95972						

ICD-10-CM Diagnosis Code	Description
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
G54.0	Brachial plexus disorders
G54.6	Phantom limb syndrome with pain
G54.9	Dorsalgia, unspecified
G56.40	Causalgia of unspecified upper limb
G56.41	Causalgia of right upper limb
G56.42	Causalgia of left upper limb
G56.43	Causalgia of bilateral upper limbs
G56.81	Other specified mononeuropathies of right upper limb
G56.82	Other specified mononeuropathies of left upper limb
G57.70	Causalgia of unspecified lower limb
G57.71	Causalgia of right lower limb
G57.72	Causalgia of left lower limb
G57.73	Causalgia of bilateral lower limbs
G57.80	Other specified mononeuropathies of unspecified lower limb
G57.81	Other specified mononeuropathies of right lower limb
G57.82	Other specified mononeuropathies of left lower limb
G57.83	Other specified mononeuropathies of bilateral lower limbs

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Procedure Codes	
G58.0	Intercostal neuropathy
G60.0	Hereditary motor and sensory neuropathy
G60.2	Neuropathy in association with hereditary ataxia
G60.3	Idiopathic progressive neuropathy
G60.8	Other hereditary and idiopathic neuropathies
G63	Polyneuropathy in diseases classified elsewhere
G65.1	Sequelae of other inflammatory polyneuropathy
G89.0	Central pain syndrome
G89.21	Chronic pain due to trauma
G89.28	Other Chronic postprocedural pain
G89.29	Other Chronic Pain
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
G90.50	Complex regional pain syndrome I unspecified
G90.511	Complex regional pain syndrome I of right upper limb
G90.512	Complex regional pain syndrome I of left upper limb
G90.513	Complex regional pain syndrome I of upper limb, bilateral
G90.519	Complex regional pain syndrome I of unspecified upper limb
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.529	Complex regional pain syndrome I of unspecified lower limb
G90.59	Complex regional pain syndrome I of other specified site
M34.83	Systemic sclerosis with polyneuropathy
M50.10	Cervical disc disorder with radiculopathy, unspecified cervical region
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.120	Mid-cervical disc disorder, unspecified level
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy
M50.13	Cervical disc disorder with radiculopathy, cervicothoracic region
M51.14	Intervertebral disc disorders with radiculopathy, thoracic region
M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M54.10	Radiculopathy, site unspecified
M54.12	Radiculopathy, cervical region
M54.13	Radiculopathy, cervicothoracic region

Procedure Codes	
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.30	Sciatica, unspecified side
M54.31	Sciatica, right side
M54.32	Sciatica, left side
M54.40	Lumbago with sciatica, unspecified side
M54.41	Lumbago with sciatica, right side
M54.42	Lumbago with sciatica, left side
M54.5	Low back pain
M54.50	Low back pain, unspecified
M54.51	Vertebrogenic low back pain
M54.59	Other low back pain
M54.6	Pain in thoracic spine
M54.81	Occipital neuralgia
M54.89	Other dorsalgia
M79.10	Myalgia, unspecified site
M96.1	Postlaminectomy syndrome, not elsewhere classified
R52	Pain, unspecified

IX. REFERENCES

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1. *Eldabe, SS, Buchser, EE, Duarte, RR. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. Pain Med, 2016 Jan 28; 17(2). PMID 26814260*
2. *Sivanesan, EE, Bicket, MM, Cohen, SS. Retrospective analysis of complications associated with dorsal root ganglion stimulation for pain relief in the FDA MAUDE database. Reg Anesth Pain Med, 2019 Jan 15; 44(1). PMID 30640660*
3. *U.S. Food and Drug Administration. Conduct a trial stimulation period before implanting a spinal cord stimulator (SCS) - letter to health care providers. September 3, 2020.*
4. *Food and Drug Administration. Cordis Programmable Neural Stimulator: Premarket Approval.*
5. *Turk DC, Dworkin RH, Allen RR, et al. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. Pain. Dec 2003; 106(3):337-345. PMID 14659516*
6. *Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. Jan 2005; 113(1-2):9-19. PMID 15621359*

7. *Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. Feb 2008; 9(2):105-121. PMID 18055266*
8. *Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain. Dec 1985; 23(4):345-356. PMID 4088697*
9. *Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore. Mar 1994; 23(2):129-138. PMID 8080219*
10. *Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). Nov 15, 2000; 25(22):2940-2952; discussion 2952. PMID 11074683*
11. *Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine (Phila Pa 1976). Jan 1, 2008; 33(1):90-94. PMID 18165753*
12. *Wells GA, Tugwell P, Kraag GR, et al. Minimum important difference between patients with rheumatoid arthritis: the patient's perspective. J Rheumatol. Mar 1993; 20(3):557-560. PMID 8478873*
13. *Kosinski M, Zhao SZ, Dedhiya S, et al. Determining minimally important changes in generic and disease-specific health-related quality of life questionnaires in clinical trials of rheumatoid arthritis. Arthritis Rheum. Jul 2000; 43(7):1478-1487. PMID 10902749*
14. *Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. Arthritis Rheum. Aug 2001; 45(4):384-391. PMID 11501727*
15. *Beck ATS, R.A. Beck Depression Inventory. San Antonio, TX: Psychological Corporation; 1993.*
16. *Curran SL, Andrykowski MA, Studts JL. Short Form of the Profile of Mood States (POMS-SF): Psychometric information. Psychol Assess 1995; 7:80-83.*
17. *Visnjevac O, Costandi S, Patel BA, et al. A comprehensive outcome-specific review of the use of spinal cord stimulation for complex regional pain syndrome. Pain Pract. Apr 2017; 17(4):533-545. PMID 27739179*
18. *O'Connell NE, Wand BM, McAuley J, et al. Interventions for treating pain and disability in adults with complex regional pain syndrome. Cochrane Database Syst Rev. Apr 30 2013(4):CD009416. PMID 23633371*
19. *Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: a systematic review. Pain Physician. Jan 2016; 19(1):E33-54. PMID 26752493*
20. *Kapural L, Peterson E, Provenzano DA, et al. Clinical evidence for spinal cord stimulation for failed back surgery syndrome (FBSS): systematic review. Spine (Phila Pa 1976). Jul 15, 2017;42 Suppl 14:S61-S66. PMID 28441313*
21. *Frey ME, Manchikanti L, Benyamin RM, et al. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. Pain Physician. Mar-Apr 2009; 12(2):379-397. PMID 19305486*

22. *Head J, Mazza J, Sabourin V, et al. Waves of Pain Relief: A Systematic Review of Clinical Trials in Spinal Cord Stimulation Waveforms for the Treatment of Chronic Neuropathic Low Back and Leg Pain. World Neurosurg. Nov 2019; 131:264-274.e3. PMID 31369885*
23. *Duarte RV, Nevitt S, Maden M, et al. Spinal cord stimulation for the management of painful diabetic neuropathy: a systematic review and meta-analysis of individual patient and aggregate data. Pain. Nov 01, 2021; 162(11): 2635-2643. PMID 33872236*
24. *Raghu ALB, Parker T, Aziz TZ, et al. Invasive Electrical Neuromodulation for the Treatment of Painful Diabetic Neuropathy: Systematic Review and Meta-Analysis. Neuromodulation. Jan 2021; 24(1): 13-21. PMID 32588933*
25. *Strand NH, Burkey AR. Neuromodulation in the Treatment of Painful Diabetic Neuropathy: A Review of Evidence for Spinal Cord Stimulation. J Diabetes Sci Technol. Mar 2022; 16(2): 332-340. PMID 34842478*
26. *O'Connell NE, Ferraro MC, Gibson W, et al. Implanted spinal neuromodulation interventions for chronic pain in adults. Cochrane Database Syst Rev. Dec 02, 2021; 12: CD013756. PMID 34854473*
27. *North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery. Dec 2005;56(1):98-106; discussion 106-107. PMID 15617591*
28. *Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain. Nov 2007; 132(1-2):179-188. PMID 17845835*
29. *Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: a randomized double-blind placebo-controlled study. Neuromodulation. Jul-Aug 2013;16(4):363-369; discussion 369. PMID 23425338*
30. *Kapural L, Yu C, Doust MW, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial. Anesthesiology. Oct 2015; 123(4):851-860. PMID 26218762*
31. *De Andres J, Monsalve-Dolz V, Fabregat-Cid G, et al. Prospective, randomized blind effect-on-outcome study of conventional vs high-frequency spinal cord stimulation in patients with pain and disability due to failed back surgery syndrome. Pain Med. Dec 1, 2017; 18(12):2401-2421. PMID 29126228*
32. *Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. Health Technol Assess. Mar 2009; 13(17): iii, ix-x, 1-154. PMID 19331797*
33. *National Institute for Health and Care Excellence (NICE). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin [TA159]. 2008*
34. *Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med. Aug 31, 2000; 343(9):618-624. PMID 10965008*

35. *Kemler MA, De Vet HC, Barendse GA, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol. Jan 2004; 55(1):13-18. PMID 14705107*
36. *Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. Diabetes Care. Nov 2014;37(11):3016-3024. PMID 25216508*
37. *Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. Oct 2008; 63(4):762-770; discussion 770. PMID 18981888*
38. *Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. J Neurosurg. Feb 2008; 108(2):292-298. PMID 18240925*
39. *de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. Pain. Nov 2014; 155(11):2426-2431. PMID 25180016*
40. *Duarte RV, Andronis L, Lenders MW, et al. Quality of life increases in patients with painful diabetic neuropathy following treatment with spinal cord stimulation. Qual Life Res. Jul 2016; 25(7):1771-1777. PMID 26694963*
41. *Rigoard, PP, Basu, SS, Desai, MM, Taylor, RR, Annemans, LL, Tan, YY, Johnson, MM, Van den Abeele, CC, North, RR. Multicolumn Spinal Cord Stimulation for Predominant Back Pain in Failed Back Surgery Syndrome Patients: A Multicenter Randomized Controlled Trial. Pain, 2019 Feb 6. PMID 30720582*
42. *Bicket MC, Dunn RY, Ahmed SU. High-frequency spinal cord stimulation for chronic pain: pre-clinical overview and systematic review of controlled trials. Pain Med. Dec 2016; 17(12):2326-2336. PMID 28025366*
43. *Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. Neurosurgery. Nov 2016; 79(5):667-677. PMID 27584814*
44. *Al-Kaisy A, Palmisani S, Smith TE, et al. Long-term improvements in chronic axial low back pain patients without previous spinal surgery: a cohort analysis of 10-kHz high-frequency spinal cord stimulation over 36 months. Pain Med. Oct 24, 2017. PMID 29077889*
45. *Hou S, Kemp K, Grabois M. A systematic evaluation of burst spinal cord stimulation for chronic back and limb pain. Neuromodulation. Jun 2016; 19(4):398-405. PMID 27139915*
46. *De Ridder D, Plazier M, Kamerling N, et al. Burst spinal cord stimulation for limb and back pain. World Neurosurg. Nov 2013; 80(5):642-649.e641. PMID 23321375*
47. *De Ridder D, Vanneste S, Plazier M, et al. Burst spinal cord stimulation: toward paresthesia-free pain suppression. Neurosurgery. May 2010; 66(5):986-990. PMID 20404705*

48. *Schu S, Slotty PJ, Bara G, et al. A prospective, randomised, double-blind, placebo-controlled study to examine the effectiveness of burst spinal cord stimulation patterns for the treatment of failed back surgery syndrome. Neuromodulation. Jul 2014; 17(5):443-450. PMID 24945621*
49. *Kriek N, Groeneweg JG, Stronks DL, et al. Preferred frequencies, and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. Eur J Pain. Mar 2017; 21(3):507-519. PMID 27714945*
50. *Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: results from a prospective, randomized controlled trial using a novel burst waveform. Neuromodulation. Jan 2018; 21(1):56-66. PMID 28961366*
51. *Chang Chien GC, Mekhail N. Alternate intraspinal targets for spinal cord stimulation: a systematic review. Neuromodulation. Oct 2017; 20(7):629-641. PMID 28160397*
52. *Vuka, II, Marciu, TT, Doenovi, SS, Ferhatovi Hamzi, LL, Vui, KK, Sapunar, DD, Puljak, LL. Neuromodulation with electrical field stimulation of dorsal root ganglion in various pain syndromes: a systematic review with focus on participant selection. J Pain Res, 2019 Mar 19; 12:803-830. PMID 30881093*
53. *Huygen FJPM, Kallewaard JW, Nijhuis H, et al. Effectiveness and Safety of Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain: A Pooled Analysis. Neuromodulation. Feb 2020; 23(2):213-221. PMID 31730273*
54. *Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. Apr 2017; 158(4):669-681. PMID 28030470*
55. *Eldabe S, Duarte R, Gulve A, et al. Analgesic Efficacy of "Burst" and Tonic (500 Hz) Spinal Cord Stimulation Patterns: A Randomized Placebo-Controlled Crossover Study. Neuromodulation. Apr 2021; 24(3): 471-478. PMID 33251662*
56. Bicket MC, Dunn RY, Ahmed SU. High-Frequency Spinal Cord Stimulation for Chronic Pain: Pre-Clinical Overview and Systematic Review of Controlled Trials. Pain Med. Dec 2016; 17(12): 2326-2336. PMID 28025366
57. Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: a randomized double-blind placebo-controlled study. Neuromodulation. Jul-Aug 2013; 16(4): 363-9; discussion 369. PMID 23425338
58. Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Jun 01, 2021; 78(6): 687-698. PMID 33818600
59. Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. Diabetes Care. Jan 01, 2022; 45(1): e3-e6. PMID 34844993
60. Moman RN, Peterson AA, Maher DP, et al. Infectious Complications of Dorsal Root Ganglion Stimulation: A Systematic Review and Pooled Analysis of Incidence. Neuromodulation. Jun 06, 2021. PMID 34096135

61. *Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Axium Neurostimulator System. 2016;*
62. *Mekhail, NN, Deer, TT, Kramer, JJ, Poree, LL, Amirdelfan, KK, Grigsby, EE, Staats, PP, Burton, AA, Burgher, AA, Scowcroft, JJ, Golovac, SS, Kapural, LL, Paicius, RR, Pope, JJ, Samuel, SS, McRoberts, WW, Schaufele, MM, Kent, AA, Raza, AA, Levy, RR. Paresthesia-Free Dorsal Root Ganglion Stimulation: An ACCURATE Study Sub-Analysis. Neuromodulation, 2019 Mar 13. PMID 30861286*
63. *Schu S, Gulve A, ElDabe S, et al. Spinal cord stimulation of the dorsal root ganglion for groin pain-a retrospective review. Pain Pract. Apr 2015; 15(4):293-299. PMID 24690212*
64. *Liem L, Russo M, Huygen FJ, et al. One-year outcomes of spinal cord stimulation of the dorsal root ganglion in the treatment of chronic neuropathic pain. Neuromodulation. Jan 2015; 18(1):41-48; discussion 48-49. PMID 25145467*
65. *Huygen, FF, Liem, LL, Nijhuis, HH, Cusack, WW, Kramer, JJ. Evaluating Dorsal Root Ganglion Stimulation in a Prospective Dutch Cohort. Neuromodulation, 2018 Aug 7;22(1). PMID 30079622*
66. *Morgalla, MM, Fortunato, MM, Lepski, GG, Chander, BB. Dorsal Root Ganglion Stimulation (DRGS) for the Treatment of Chronic Neuropathic Pain: A Single-Center Study with Long-Term Prospective Results in 62 Cases. Pain Physician, 2018 Jul 27; 21(4). PMID 30045604*
67. *Eldabe, SS, Espinet, AA, Wahlstedt, AA, Kang, PP, Liem, LL, Patel, NN, Vesper, JJ, Kimber, AA, Cusack, WW, Kramer, JJ. Retrospective Case Series on the Treatment of Painful Diabetic Peripheral Neuropathy With Dorsal Root Ganglion Stimulation. Neuromodulation, 2018 Mar 27; 21(8). PMID 29575331*
68. *Kallewaard, JJ, Nijhuis, HH, Huygen, FF, Wille, FF, Zuidema, XX, van de Minkelis, JJ, Raza, AA. Prospective Cohort Analysis of DRG Stimulation for Failed Back Surgery Syndrome Pain Following Lumbar Discectomy. Pain Pract, 2018 Oct 1; 19(2). PMID 30269439*
69. *Piedade, GG, Vesper, JJ, Chatzikalfas, AA, Slotty, PP. Cervical and High-Thoracic Dorsal Root Ganglion Stimulation in Chronic Neuropathic Pain. Neuromodulation, 2019 Jan 9. PMID 30620789*
70. *Kallewaard, JJ, Edelbroek, CC, Terheggen, MM, Raza, AA, Geurts, JJ. A Prospective Study of Dorsal Root Ganglion Stimulation for Non-Operated Discogenic Low Back Pain. Neuromodulation, 2019 Mar 2. PMID 30821901*
71. *Deer, TT, Pope, JJ, Hunter, CC, Falowski, SS, Kapural, LL, Kramer, JJ, Levy, RR. Safety Analysis of Dorsal Root Ganglion Stimulation in the Treatment of Chronic Pain. Neuromodulation, 2019 Mar 13. PMID 30861617*
72. *Weiner RL, Yeung A, Montes Garcia C, et al. Treatment of FBSS low back pain with a novel percutaneous DRG wireless stimulator: pilot and feasibility study. Pain Med. Oct 2016; 17(10):1911-1916. PMID 27125284*
73. *Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia. Cochrane Database Syst Rev. Feb 28, 2013; 2(2):CD004001. PMID 23450547*

74. *Klomp HM, Steyerberg EW, Habbema JD, et al. What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia? Ann Vasc Surg. May-Jun 2009; 23(3):355-363. PMID 19128928*
75. *Klomp HM, Spincemaille GH, Steyerberg EW, et al. Spinal-cord stimulation in critical limb ischaemia: a randomised trial. ESES Study Group. Lancet. Mar 27, 1999; 353(9158):1040-1044. PMID 10199350*
76. *Abu Dabrh AM, Steffen MW, Asi N, et al. Nonrevascularization-based treatments in patients with severe or critical limb ischemia. J Vasc Surg. Nov 2015; 62(5):1330-1339 e1313. PMID 26409842*
77. *Pan X, Bao H, Si Y, et al. Spinal cord stimulation for refractory angina pectoris: a systematic review and meta- analysis. Clin J Pain. Jun 2017; 33(6):543-551. PMID 27875377*
78. *Tsigaridas N, Naka K, Tsapogas P, et al. Spinal cord stimulation in refractory angina. A systematic review of randomized controlled trials. Acta Cardiol. Apr 2015; 70(2):233-243. PMID 26148385*
79. *Zipes DP, Svorkdal N, Berman D, et al. Spinal cord stimulation therapy for patients with refractory angina who are not candidates for revascularization. Neuromodulation. Nov-Dec 2012; 15(6):550-558; discussion 558-559. PMID 22494013*
80. *Lanza GA, Grimaldi R, Greco S, et al. Spinal cord stimulation for the treatment of refractory angina pectoris: a multicenter randomized single-blind study (the SCS-ITA trial). Pain. Jan 2011; 152(1):45-52. PMID 21084162*
81. *Torre-Amione G, Alo K, Estep JD, et al. Spinal cord stimulation is safe and feasible in patients with advanced heart failure: early clinical experience. Eur J Heart Fail. Jul 2014; 16(7):788-795. PMID 24961194*
82. *Zipes DP, Neuzil P, Theres H, et al. Determining the feasibility of spinal cord neuromodulation for the treatment of chronic systolic heart failure: The DEFEAT-HF Study. JACC Heart Fail. Feb 2016; 4(2):129-136. PMID 26682789*
83. *Lihua P, Su M, Zejun Z, et al. Spinal cord stimulation for cancer-related pain in adults. Cochrane Database Syst Rev. Feb 28, 2013; 2(2):CD009389. PMID 23450600*
84. *Peng L, Min S, Zejun Z, et al. Spinal cord stimulation for cancer-related pain in adults. Cochrane Database Syst Rev. Jun 29, 2015; 6(6):CD009389. PMID 26121600*
85. *Mekhail NA, Mathews M, Nageeb F, et al. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. Pain Pract. Mar-Apr 2011; 11(2):148-153. PMID 21371254*
86. *Lanza GA, Barone L, Di Monaco A. Effect of spinal cord stimulation in patients with refractory angina: evidence from observational studies. Neuromodulation. Nov-Dec 2012; 15(6):542-549; discussion 549. PMID 22364309*
87. *Dworkin RH, O'Connor AB, Kent J, et al. Interventional management of neuropathic pain: NeuPSIG recommendations. Pain. Nov 2013; 154(11):2249-2261. PMID 23748119*
88. *Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. Apr 2013; 16(2 Suppl):S49-283. PMID 23615883*

89. Aman MM, Mahmoud A, Deer T, et al. The American Society of Pain and Neuroscience (ASPN) Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain. J Pain Res. 2021; 14: 2139-2164. PMID 34295184
90. *Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. Jan 2007; 10(1):7-111. PMID 17256025*
91. *Benzon, HH, Connis, RR, De Leon-Casasola, OO, Glass, DD, Korevaar, WW, Cynwyd, BB, Mekhail, NN, Merrill, DD, Nickinovich, DD, Rathmell, JJ, Sang, CC, Simon, DD. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology, 2010 Feb 4; 112(4). PMID 20124882*
92. *Deer TR, Pope JE, Lamer TJ, et al. The Neuromodulation Appropriateness Consensus Committee on Best Practices for Dorsal Root Ganglion Stimulation. Neuromodulation. Jan 2019; 22(1):1-35. PMID 30246899*
93. *Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7). 1995*
94. *Mannheimer C, Eliasson T, Augustinsson LE, et al. Electrical stimulation versus coronary artery bypass surgery in severe angina pectoris: the ESBY study. Circulation. 1998;97(12):1157-1163. doi:10.1161/01.cir.97.12.1157 PMID: 9537342.*
95. *Sayed D, Grider J, Strand N, et al. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain [published correction appears in J Pain Res. 2022 Dec 24;15:4075-4076]. J Pain Res. 2022;15:3729-3832. Published 2022 Dec 6. doi:10.2147/JPR.S386879PMID: 36510616*
96. *Sun L, Peng C, Joosten E, et al. Spinal Cord Stimulation and Treatment of Peripheral or Central Neuropathic Pain: Mechanisms and Clinical Application. Neural Plast. 2021;2021:5607898. Published 2021 Oct 21. doi:10.1155/2021/5607898 PMID: 34721569*
97. *Bates D, Schultheis BC, Hanes MC, et al. A Comprehensive Algorithm for Management of Neuropathic Pain [published correction appears in Pain Med. 2023 Feb 1;24(2):219]. Pain Med. 2019;20(Suppl 1):S2-S12. doi:10.1093/pm/pnz075*
98. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.25, Spinal Cord and Dorsal Root Ganglion Stimulation, May 2023*

X. POLICY HISTORY

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MP-1.069	**5/10/19 Minor review.** Changed Dorsal root ganglion neurostimulation from investigational to medically necessary for the treatment of severe and chronic pain of the trunk or limbs. Background, summary of evidence and references updated. Changed title to Spinal Cord and Dorsal Root Ganglion Stimulation. Previously Spinal Cord Stimulation. Coding reviewed and revised.
	5/4/20 Consensus review. No change to policy statements. Updated regulatory status and references. Coding reviewed; unspecified diagnosis codes added.
	4/5/2021 Consensus review. No change to policy statement. Coding reviewed with no changes. Rationale updated.

POLICY TITLE	SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION
POLICY NUMBER	MP 1.069

	8/5/2021 Minor review. Added criteria for temporary trial spinal cord stimulation (SCS) device to policy guidelines.
	9/7/21: Administrative review. Added new ICD-10 codes. Effective date 10/1/21.
	06/23/2022 Minor review. Added painful diabetic neuropathy to list of common indications for neuropathic pain for temporary and permanent spinal cord stimulation as well as dorsal root ganglion neurostimulation. Added ICD10 codes E10.40, E10.41, E10.42, E11.40, E11.41, E11.42, E13.40, E13.41, E13.42. FEP language updated. Revised Background and Rationale. New references added.
	12/1/2022 Administrative Review. Added new codes C1826 & C1827. Effective date 1/1/2023.
	06/12/2023 Consensus Review. No change to policy stance. Updated background. New ref.

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