Medical Policy

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Title: Spinal Cord and Dorsal Root Ganglion Stimulation

Related Policies:	▪ *Deep Brain Stimulation*

Professional / Institutional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • Standard spinal cord stimulation	Comparators of interest are: • Medical therapy • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • High-frequency spinal cord stimulation	Comparators of interest are: • Standard spinal cord stimulation • Medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

Populations	Interventions	Comparators	Outcomes
		• Surgical therapy	• Medication use • Treatment-related morbidity
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • Dorsal root ganglion neurostimulation	Comparators of interest are: • Standard spinal cord stimulation • Medical therapy • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With critical limb ischemia	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medication therapy • Revascularization surgery • Amputation	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With treatment-refractory angina pectoris	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy • Coronary revascularization	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With heart failure	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy • Coronary revascularization	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With cancer-related pain	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

DESCRIPTION

Spinal cord stimulation delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain; this is achieved through a surgically implanted spinal cord stimulation device, which comes equipped with a radiofrequency receiver. The neurostimulator device is also issued with a standard power source (battery) that can be implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

OBJECTIVE

The objectives of this evidence review is to determine 1) whether the use of spinal cord stimulation and dorsal root ganglion neurostimulation for treating patients with treatment-refractory chronic pain of the trunk or limbs improves the net health outcome, and 2) whether the use of spinal cord stimulation for treating patients with critical limb ischemia, refractory angina, heart failure, and cancer-related pain improves the net health outcome.

BACKGROUND

Spinal cord stimulation 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 (CPRS; ie, chronic reflex sympathetic dystrophy). There has also been interest in spinal cord stimulation as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest pain.

Spinal Cord Stimulation

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.

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 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns. There are 2 basic types of power source: 1 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.

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 8 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 spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Dorsal Root Ganglion Neurostimulation
Dorsal root ganglion neurostimulation (or dorsal root ganglion stimulation, DRGS) uses the same epidural approach technique as spinal cord stimulation but targets a different anatomical target, the dorsal root ganglion. Dorsal root ganglia, situated within the spine as clusters of nerve cell bodies, serve as the "sensory gate" for pain signals entering the spinal cord. DRGS seeks to modulate the activity of these nerve cell bodies, potentially intercepting or diminishing pain signals before they reach the spinal cord. DRGS proves particularly efficacious for localized or chronic nerve pain conditions, such as complex regional pain syndrome, post-amputation pain, and pain following specific surgical procedures. It allows for more precise targeting of specific nerves and pain areas compared to SCS, potentially leading to better pain relief with fewer side effects. Moreover, DRGS may induce less paresthesia (tingling or numbness) than SCS, owing to its focused and precise stimulation. Recovery from DRGS implantation typically spans 6-8 weeks, during which patients are advised to refrain from strenuous activities.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. High frequency devices use electrical stimulation with a frequency of 10,000 Hz. In 2016, the U.S. Food and Drug Administration (FDA) approved a clinician programmer application that allows a SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. 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 1 ms. Other neurostimulators target the dorsal root ganglion.

REGULATORY STATUS
A large number of 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. FDA Cleared or Approved Devices for Spinal Cord and Dorsal Root Ganglion Stimulation

Device	Manufacturer	Product code	Original clearance/approval date	Original 510(k) or 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

Device	Manufacturer	Product code	Original clearance/approval date	Original 510(k) or PMA number	Indication
					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 (now Curonix)	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; Eterna Spinal Cord Stimulation (SCS) System;Prodigy, Proclaim, and Proclaim XR Spinal Cord Stimulation (SCS) Systems	St. Jude Medical/ Abbott Medical	LGW; QRB	Nov 2001	P010032	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 and leg pain, and diabetic peripheral neuropathy of the lower extremities.
Restore, Itrel, Synergy, Intellis, And Vanta Spinal Cord Stimulation Systems	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: • FBS or low back syndrome or failed back • Radicular pain

Device	Manufacturer	Product code	Original clearance/approval date	Original 510(k) or PMA number	Indication
					syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk • Postlaminectomy pain • Multiple back operations • Unsuccessful disk surgery • Refractory DDD/herniated disk pain • Peripheral causalgia • Epidural fibrosis • Arachnoiditis or lumbar adhesive arachnoiditis • CRPS, 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
Evoke SCS System	Saluda Medical Pty Ltd	LGW	Feb 2022	P190002	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.
Senza SCS Systems	Nevro Corporation	LGW	May 2015	P130022	Chronic intractable pain of the trunk and/or limbs, including

Device	Manufacturer	Product code	Original clearance/approval date	Original 510(k) or PMA number	Indication
					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)
Nalu Neurostimulation System	Nalu Medical, Inc	GZB	Mar 2019	K183047	Chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain
Prospera Spinal Cord Stimulation (SCS) System	Biotronik NRO, Inc	LGW	Mar 2023	P210037	Chronic, intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain, resulting from any of the following: 1) FBS or low back syndrome or failed back; 2) Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or; 3) Herniated disk; 4) Postlaminectomy pain; 5) Multiple back operations; 6) Unsuccessful disk

Device	Manufacturer	Product code	Original clearance/approval date	Original 510(k) or PMA number	Indication
					surgery; 7) DDD/herniated disk pain refractory to conservative and surgical interventions; 8) Peripheral causalgia; 9) Epidural fibrosis;10) Arachnoiditis or lumbar adhesive arachnoiditis; and11) CRPS, RSD, or causalgia.

CRPS: Complex regional pain syndrome; DDD: degenerative disk disease; FBS: failed back syndrome; PMA: premarket approval; RSD, reflex sympathetic dystrophy; SCS: spinal cord stimulation.
[a] Withdrawn in 2016[1,]

POLICY

A. Spinal cord stimulation and dorsal root ganglion neurostimulation 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 performed according to policy guidelines.

B. Spinal cord stimulation and dorsal root ganglion neurostimulation is considered **experimental / investigational** in all other situations, including, but not limited to, treatment of critical limb ischemia to forestall amputation and treatment of refractory angina pectoris, heart failure, and treatment of non-neuropathic cancer-related pain.

C. Wireless injectable dorsal root ganglion neurostimulation is considered **experimental / investigational**.

POLICY GUIDELINES

A. Individual selection focuses on determining whether the individual is refractory to other types of treatment. The following considerations shall **ALL** apply:
   1. The treatment is used when reasonable conservative treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated, **AND**
   2. 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, and peripheral 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), **AND**
   3. No serious untreated drug habituation exists, **AND**
   4. Demonstration of at least 70% pain relief during a typical 5 to 7 day temporary trial electrode array implant prior to permanent implantation, **AND**
   5. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the individual are available, **AND**
   6. Psychological evaluation prior to trial implantation has been performed and indicates no contraindications to spinal cord stimulation.

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

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review was created using the PubMed database. The most recent literature update was performed through March 12, 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

STANDARD SPINAL CORD STIMULATION FOR REFRACTORY CHRONIC TRUNK OR LIMB PAIN

Clinical Context and Therapy Purpose

The purpose of spinal cord stimulation (SCS) in individuals who have treatment-refractory chronic trunk or limb pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with treatment-refractory chronic pain of the trunk or limbs. Examples of treatment-refractory chronic pain include failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) (ie, reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy.

Interventions

The therapy being considered is standard SCS alone. SCS uses low-level epidural electrical stimulation of the spinal cord dorsal columns. Its mechanism of action is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits. SCS devices consist of several components: (1) the lead delivering 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. The lead may incorporate 4 to 8 electrodes, depending on the complexity of the pain pattern. The U.S. Food and Drug Administration (FDA) recommends a trial period in which the electrode is temporarily implanted in the epidural space prior to the permanent implantation. Standard SCS devices operate under a frequency of 100 to 1000 Hz.

In 2016, a supplement to a standard SCS device (in the form of a clinician programmer application), which allows for the provision of burst stimulation, was approved by the FDA.

Comparators

The following practice is currently being used to treat individuals with treatment-refractory chronic pain of the trunk or limbs: medical therapy or surgical therapy.

Outcomes

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[2,] The IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (Table 2).[3,4,]

Table 2. Health Outcome Measures Relevant to Trials of Chronic Pain

Domain	Outcome Measure	Description	Clinically Meaningful Difference
Pain intensity			
	• Numeric rating scale • Verbal rating scale • Visual analog scale	Rating of pain intensity on a scale of 0 (no pain) to 10 (pain as bad as you can imagine) or from 0 to 10 cm	• Minimally important: 10% to 20% decrease • Moderately important: ≥ 30% decrease • Substantial: ≥50% decrease[4,]
Physical functioning			
	Disease-specific	***Measures of the interference of pain with physical functioning***	
	• Multidimensional Pain Inventory[5,] Interference Scale	• 60 items, self-report • 12 subscales: interference, support, pain severity, self-control, negative mood, punishing responses, solicitous responses, distracting responses, household chores, outdoor	• ≥0.6-point decrease[4,]

Domain	Outcome Measure	Description	Clinically Meaningful Difference
		work, activities away from home, and social activities • Items rated on 0- to 6-point scale • Interference subscale score calculated by mean of subscale items	
•	• Brief Pain Inventory[6,] Interference Scale	• 7 items, self-report • Measures intensity, quality, relief, and interference of pain and patients' ideas of the causes of pain • Mean of the 7 interference items can be used as a measure of pain interference	• 1-point decrease[4,]
•	• Oswestry Disability Index (ODI)[7,]	Measures functional impairment due to lower back pain: • 10 sections, self-report • Sections: intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel • Each section is scored on a 0 to 5 scale with 5 indicating the greatest disability • Total score calculated by taking the mean of the section scores and multiplying by 100	• 10 points[8,]
•	***General***	***Generic measure of physical functioning***	
	• 36-Item Short Form Health Survey	Measure overall health status: • 36 items, self-report • 8 domains: physical function, physical role, general health, bodily pain, mental health, social function, vitality/fatigue, and emotional role • Physical Component Summary and Mental Component Summary scores	• 5 to 10 points[9,10,11,]

Domain	Outcome Measure	Description	Clinically Meaningful Difference
		are aggregate scores that can be calculated • Higher scores indicate better health status	
Emotional functioning			
	• Beck Depression Inventory (BDI)[12,]	• 21 items, self-report • Measures severity of current symptoms of depressive disorders • Scores range from 0 to 63	• ≥5-point decrease[4,]
•	• Profile of Mood States[13,]	• 65 items, self-report • Measures total mood disturbance with 6 subscales: tension, depression, anger, vigor, fatigue, and confusion • Scores range from 0 to 200	• ≥10- to 15-point decrease[4,]
Global rating of improvement			
	• Patient Global Impression (PGI) of Change	• Single-item, self-rating • 7-point scale ranging from 1 (very much worse) to 7 (very much improved)	• Minimally important: minimally improved • Moderately important: much improved • Substantial: very much improved[4,]

Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration, failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache and neurological damage.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

STANDARD SPINAL CORD STIMULATION

REVIEW OF EVIDENCE

Systematic Reviews

Numerous systematic reviews have been conducted assessing the efficacy of SCS for a variety of chronic pain conditions, including CRPS[14,15], spinal pain[16,17], FBSS[18], painful diabetic neuropathy[19,20,21,22,23], and mixed chronic pain conditions.[24,25] However, each of these reviews only included a subset of the RCTs of standard SCS; evidence from the relevant individual RCTs is discussed in the next section.

Huygen et al (2024) performed a meta-analysis to assess the efficacy of SCS therapies in comparison with conventional medical management (CMM).[26] RCTs published through 2022 were considered for inclusion that compared SCS therapies with sham (placebo) and/or CMM or standard treatments for adults suffering from chronic back or leg pain who had not previously utilized SCS. The primary outcomes focused on pain-related metrics, including pain intensity (measured by visual analog scale) and the proportion of patients achieving at least 50% pain relief (responder rate) in the back or leg. Additionally, the study considered quality of life (measured by EQ-5D index score) and functional disability (measured by the ODI score).

The network meta-analysis incorporated 13 studies involving 1561 patients, comparing conventional and novel SCS therapies (eg, high-frequency stimulation, burst stimulation, closed loop, and differential target multiplexed) with CMM across six outcomes at a 6-month follow-up. Both conventional and novel SCS therapies demonstrated superior efficacy compared to CMM in terms of responder rates in the back (conventional SCS: odds ratio [OR], 3.00; 95% Confidence Interval [CI], 1.49 to 6.72; novel SCS: OR, 8.76; 95% CI, 3.84 to 22.31), pain intensity in the back (conventional SCS: mean difference [MD], -1.17; 95% CI, -1.64 to -0.70; novel SCS: MD, -2.34; 95% CI, -2.96 to -1.73), pain intensity in the leg (conventional SCS: MD, -2.89; 95% CI, -4.03 to -1.81; novel SCS: MD, -4.01; 95% CI, -5.31 to -2.75), and EQ-5D index score (conventional SCS: MD, 0.15; 95% CI, 0.09 to 0.21; novel SCS: MD, 0.17; 95% CI, 0.13 to 0.21). Additionally, conventional SCS showed superior results in functional disability compared to CMM (MD, -7.10; 95% CI, -10.91 to -3.36). No statistically significant differences were observed for other comparisons. This meta-analysis suggests that SCS therapies for chronic pain in the back and/or lower extremities offer greater improvements in pain relief compared to CMM, underscoring the potential of SCS therapies as effective and valuable options in chronic pain management.

Randomized Controlled Trials

Seven RCTs (in 12 publications)[27,28,29,30,31,32,33,34,35,36,](N= range, 36 to 218 patients) have evaluated standard SCS for various chronic pain conditions (Table 3). Patient populations had FBSS, diabetic neuropathy, and CRPS. The comparators were primarily conventional medical management, although 1 RCT compared SCS with reoperation for failed back surgery syndrome, another compared SCS with physical therapy and one compared closed-loop SCS with open-loop SCS. All RCTs reported results at 6 months. The most common primary outcome reported was a responder outcome of 50% reduction in pain; Kemler et al (2000) reported the absolute change in visual analog scale (VAS) pain score.[30] Consistent with clinical practice, RCTs included a trial period of SCS, usually a few days to a week. Patients not reporting improvement in pain during the trial period did not continue receiving SCS during the remainder of follow-up. In most RCTs, these patients were included in the intention-to-treat analyses either as failures to respond or using imputation techniques. All RCTs with the responder primary outcomes reported clinically and statistically significant differences in the primary outcomes at 6 months, favoring SCS (SCS range, 39% to 63% vs. comparator range, 5% to 12%). Outcomes measuring the reduction in

analgesic use were consistently numerically larger for SCS, but not statistically significant in all studies. Four (of 5) studies did not report differences in functional, quality of life, or utility outcomes. Device-related complications ranged from 17% to 32%, with the most common being infection and discomfort or pain due to positioning or migration of electrodes or leads. However, 2 studies reported dural puncture headaches and Slangen et al (2014)[33,] reported a dural puncture headache ending in death. Two studies reported longer-term results for both treatment groups. In each, results continued to favor SCS at 2 years, but for 1 with 5 years of follow-up, results were not statistically significant at 5 years.

Table 3. Characteristics and Result of RCTs Using Standard Spinal Cord Stimulation

Study	**Population**	**Interventions**	**N at Baseline and Follow-Up**	**Results**				**Complications**
				Outcome Measures	***Intervention***	***Control***	***p***	
North et al (2005)[27,]	FBSS	• SCS + CMM • Reoperation + CMM	N=60 n at 6 mo=49	6 mo (SCS vs. reoperation)				17% device-related complications (infections, hardware technical problems)
				• Success (50% pain relief and patient satisfaction)	39%	12%	.04	
				• Stable or decreased opioids	87%	58%	.025	
				• No difference in ADLs impairment due to pain	•			
Kumar et al (2007, 2008)[28,29,]	FBSS with neuropathic pain	• SCS + CMM • CMM	N=100 n at 6 mo=93	6 mo (SCS vs. CMM)				32% device-related complications (electrode migration, infection, loss of paresthesia)
				• 50% reduction in VAS leg pain	48%	9%	<.001	
				• SF-36, favoring SCS all domains except RP	•		≤.02	

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				• ODI score	45	56	<.001	
				• Opioid use	56%	70%	.21	
				• NSAID use	34%	50%	.14	
			n at 24 mo=87	24 mo (SCS vs. CMM)				
				• 50% reduction in leg pain on VAS	37%	2%	.003	
Kemler et al (2000, 2004, 2008)[30,31,32,]	CRPS	• SCS + PT • PT	N=54 n at 6 mo=54	6 mo (SCS vs. PT)				• 25% device-related complications (dural puncture, infection, unsatisfactory placement of electrode, defective lead) • 42% reoperation rate by 5 y
•				• Reduction in VAS pain score	2.4	0.2	<.001	
				• Much improved GPE	39%	6%	.01	
				• No difference in functional outcomes or HRQOL	•			
				2 y (SCS vs. PT)				
				• Reduction in VAS pain score	2.1	0.0	<.001	
				• Much improved GPE	43%	6%	.001	
			n at 5 y=44	5 y (SCS vs. PT)				

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				• Reduction in VAS pain score	1.7	1.0	.25	
Slangen et al (2014)[33]; Zuidema et al (2022)[37]	Diabetic neuropathy of LEs	• SCS • CMM	N=36 n at 6 mo=36	6 mo (SCS vs. CMM)				2 SAEs (1 infection, 1 post-dural puncture headache ending in death)
				• Success (50% reduction in pain for 4 d or at least much improved on patient-reported global impression of change)	59%	7%	<.01	
				• Reduction in pain medication	32%	0%		
				• No differences in health utility or HRQOL	•			
			n at 24 mo=17[a]	2 y (SCS only)				
				• Success	65%			
				• No improvement in health utility vs. baseline	•			
				• ~5-point improvement in SF-36 PCS score vs. baseline	•			
			n at 8 to 10 yrs=19[a]	8 to 10 years (SCS only)				

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				• >50% reduction in VAS pain score, daytime	26%			
				• No improvement in health utility or quality of life vs. baseline	•			
De Vos et al (2014)[34,]; Duarte et al (2016)[35,]	Diabetic neuropathy of LEs	• SCS • CMM	N=60 n at 6 mo=54	6 mo (SCS vs. CMM)				18% device-related complications (infection, pain due to pulse generator or migration of lead, unsatisfactory placement of electrode)
				• 50% reduction in pain	62.5%	5%	<.001	
				• Reduction in analgesic intake (MQS score)	2.9	-0.09	NR	
				• Change in health utility	0.39	0.00	<.05	
Rigoard P (2019)[36,]	FBSS	• SCS + CMM • CMM	N=218 n at 6 mo=116	6 mo (SCS vs. CMM)				18% device-related complications, with 12% requiring surgical re-intervention
				• 50% reduction in pain	14%	5%	.04	
				• Change in SF-36 Short Form	7.5	0	<.001	
Mekhail (2020) [38,];	Chronic, intractable pain of the	• Open loop SCS	N=125 n at 12 mo=118	12 mo				

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
Mekahil (2023) [39,]	back and legs	• Closed loop SCS						
				• 50% reduction in pain	83%	61%	<.01	
				36 mo				
				• 50% reduction in pain	78%	49%	<.01	

ADL: activities of daily living; CMM: conventional medical management; CRPS: complex regional pain syndrome; FBSS: failed back surgery syndrome; GPE: global perceived effect; HRQOL: health-related quality of life; LE: lower extremities; MQS: Medication Quantification Scale III; NR: not reported; NSAID: non-steroidal anti-inflammatory drug; ODI: Oswestry Disability Index; PCS: Physical Component Summary; PT: physical therapy; RCT: randomized controlled trial; RP: role-physical; SAE: serious adverse events; SCS: spinal cord stimulation; SF-36: 36-Item Short-Form Health Survey; VAS: visual analog scale.
[a] SCS only.

Uncontrolled studies

Because RCT data are available for SCS, uncontrolled studies are discussed if they add information not available from the RCTs (eg, longer follow-up including adverse events, data on an important subgroup, etc). Rauck et al (2023) reported an analysis of long-term (>2 years) complications and explantation rates from the RELIEF registry. [40,] RELIEF is a global, multicenter, prospective registry including individuals with chronic pain who are eligible to receive neurostimulation therapy to treat pain. Adults who enrolled between between January 2013 and November 2021 and were permanently implanted with a commercially available SCS system were included in analysis (N=1289). The mean (standard deviation) age at enrollment was 58 (14) years and 57% were women. Participants reported duration of chronic pain of 12 (11) years. Study follow-up visits occurred at 6, 12, 24 and 36 months. Ninety-eight participants (8%) required an explant (annualized explant rate of 3.5%); 32 of the explants were due to inadequate pain relief. High lead impedance (5%) and lead migration/movement (5%) were the most common complications. Thirty-two serious adverse events (SAEs) related to device and 51 SAEs related to procedure were reported; device-related implant site infection (11 events) and procedure-related implant site infection (17 events) were the most common SAEs. There were 5 SAEs related to implant site pain, 3 device- or procedure-related neurological deficits, and 2 life-threatening local infections (implant site infection, meningitis). No deaths were reported.

Mekhail et al (2011) retrospectively reviewed 707 patients treated with SCS between 2000 and 2005.[41,] Patients' diagnoses included CRPS (n=345 [49%]), FBSS (n=235 [33%]), peripheral vascular disease (n=20 [3%]), visceral pain in the chest, abdomen, or pelvis (n=37 [5%]), and peripheral neuropathy (n=70 [10%]). Mean follow-up across studies was 3 years (range, 3 months to 7 years). A total of 527 (36%) of the 707 patients eventually underwent permanent implantation of an SCS device. Hardware-related complications included lead migration in 119 (23%) of 527 patients, lead connection failure in 50 (9.5%) patients, and lead break in 33 (6%) patients. Revisions or replacements corrected the hardware problems. The authors noted that rates of hardware failure have decreased due to advances in SCS technology. Documented

infection occurred in 32 (6%) of 527 patients with implants; there were 22 cases of deep infection, and 18 patients had abscesses. There was no significant difference in the infection rate by diagnosis. All cases of infection were managed by device removal.

STANDARD SPINAL CORD STIMULATION WITH BURST

Systematic Reviews

Hou et al (2016) published a systematic review of burst SCS for the treatment of chronic back and limb pain.[42,] Reviewers identified 5 studies of burst SCS in patients with intractable chronic pain of more than 3 months in duration who had failed conservative treatment. Three studies, with sample sizes of 12, 15, and 20, respectively, used randomized crossover designs to compare burst stimulation with tonic stimulation; 2 studies also included a placebo stimulation intervention. Also, there were 2 case series with sample sizes of 22 and 48 patients, respectively. Data were collected after 1 to 2 weeks of treatment. Study findings were not pooled. Using the American Academy of Neurology criteria, reviewers originally rated 4 studies as class III and 1 study as class IV. However, given the small sample sizes and short duration of follow-up of the 4 studies, all were downgraded to class IV. Overall, the level of confidence in the evidence on burst SCS for treating chronic pain without paresthesia was rated as "very low."

Randomized Controlled Trials

Deer et al (2024) conducted an US multi-center RCT (DISTINCT, NCT04479787) which enrolled 269 chronic low-back-pain patients who were not candidates for traditional spine surgery, with 162 patients randomized to burst SCS and 107 to CMM.[43,] This study allowed a crossover to the alternative treatment arm after six months. Patients underwent a trial and received a permanent implant if they reported ≥50% pain reduction. With nominal changes in baseline pain score, disability, and quality of life, 86% (70/81) of patients crossed over to the SCS arm after the 6 month follow-up, with 94% (66/70) undergoing a trial. Of these patients, 88% reported at least a 50% reduction in pain, leading 55 patients to receive a permanent implant. At the 12-month visit, 71% of these patients sustained a ≥50% pain improvement, with 24.5% experiencing an ≥80% improvement. Additionally, significant reductions in disability and improvements in quality of life measures were observed. The trial further reported that 42% of patients reduced or discontinued opioid usage. Clinical benefits noted at the 12-month mark were maintained through the 18-month follow-up.

Eight RCTs with sample sizes ranging from 12 to 269 patients were identified, 5 of which were conducted in Europe and the other in the US (Table 4). The trials by De Ridder et al (2010, 2013)[44,45,] enrolled patients with neuropathic pain, the trial by Schu et al (2014)[46,] enrolled patients with FBSS, Kriek et al (2017)[47,] enrolled patients with CRPS, Deer et al (2018)[48,] enrolled patients with chronic intractable pain of the trunk and/or limbs, and Eldabe et al (2020) enrolled patients with chronic back and leg pain.[49,] All trials compared burst stimulation with SCS. Schu et al (2014), De Ridder et al (2013), Kriek et al (2017), and Eldabe et al (2020) also compared burst with a sham stimulation group. Schu et al (2014) and Eldabe et al (2020) included patients receiving standard SCS while De Ridder et al (2010, 2013) and Deer et al (2018) included patients not previously treated with SCS. It was not clear in Kriek et al (2017) whether patients had previously received SCS. Results were reported for 1 week of stimulation in Schu et al (2014) and De Ridder et al (2013), after 2, 1-hour sessions of SCS or burst in De Ridder et al (2010), after 2 weeks of stimulation in Kriek et al (2017) and Eldabe et al (2020), and after 12 weeks of stimulation in Deer et al (2018). All trials reported reductions in absolute pain scores (numeric

rating scale or VAS). Schu et al (2014) and De Ridder et al (2013) did not account for their crossover designs in data analyses, so analyses and p values are incorrect and not reported in Table 4. De Ridder et al (2010) did not provide between-group comparisons. Kriek et al (2017) reported only per-protocol analyses. Four trials reported numerically larger reductions in pain scores with burst than with SCS; Kriek et al (2017) did not report less pain for SCS at any frequency compared with burst. In Kriek et al (2017), 48% of patients preferred the 40-Hz SCS compared with 21%, 14%, 14%, and 3% that preferred 500-Hz SCS, 1200-Hz SCS, and burst and sham, respectively. In Eldabe et al (2020), the mean reduction in pain with 500-Hz SCS was significantly greater than that seen with sham (25%; 95% CI, 8% to 38%; p=.008) or burst (28%; 95% CI, 13% to 41%; p=.002), with no significant differences in pain VAS score for burst versus sham (p=.59). The interpretation of 5 of the trials was limited by small sample sizes, short follow-up, and incorrect, inadequate, or missing statistical analyses.

The Success Using Neuromodulation with BURST (SUNBURST) trial was reported by Deer et al (2018).[48,] SUNBURST was a 12-week, multicenter, randomized, unblinded, crossover, noninferiority trial evaluating traditional SCS or burst stimulation in 100 patients with chronic pain of the trunk and/or limbs enrolled between January 2014 and May 2015. Patients were SCS naive and completed a trial stimulation period. Forty-five patients were randomized to SCS then burst, and the remaining 55 were randomized to burst then SCS. At the end of the second crossover period, patients were allowed to choose the stimulation mode they preferred and were followed for 1 year. Patients' mean age was 59 years, 60% of patients were women, and 42% of patients had FBSS while 37% had radiculopathies. The primary outcome was the difference in mean VAS score, with a noninferiority margin of 7.5 mm. Analyses were intention-to-treat with missing values imputed using the hot deck method. Also, outcomes were imputed for patients who underwent invasive procedures for pain or had medication increases. The estimated difference in the overall VAS score between burst and SCS was -5.1 mm (95% upper CI, -1.14 mm), demonstrating noninferiority (p<.001) and superiority (p<.017). The proportion of patients with a decrease in VAS score of 30% or more was 60% (60/100) during burst stimulation and 51% (51/100) during SCS. The proportion of patients whose global impression was minimally improved, moderately improved, or very much improved was approximately 74% in both groups. There were no significant differences in Beck Depression Inventory scores (p=.230). Patients were asked to rate their satisfaction levels for both periods: 78% were satisfied with both SCS and burst, 4% were dissatisfied with both SCS and burst, 7% were satisfied with SCS but not burst, and 10% were satisfied with burst but not SCS. However, more patients (71%) reported preferring burst stimulation over SCS after the 24-week crossover period. After 1 year of follow-up, 60 (68%) of the 88 patients completing follow-up reported preferring burst stimulation. The authors reported that the programming parameters were not standardized at the beginning of the study but a more standardized approach with lower amplitudes was implemented as the trial was ongoing. Trial limitations included the crossover design, which limits comparison of pain over longer periods of time, lack of blinding, and variable burst programming parameters.

Table 4. Characteristics and Result of RCTs Using Burst Spinal Cord Stimulation

Study	Population	Interventions	N at Baseline and FU	Results				Complications
2×3 crossover design				Outcome Measure	Pain	Disability	Other	
Deer et al (2024)[43]	Chronic low-back-pain	• CMM • Burst SCS	N=70 CMM patients crossed over to burst SCS arm; n=66 completed trial	Pain NRS and Back pain-related physical disability (ODI) for CMM patients crossed over to the SCS arm	88% of patients with 50% reduction in pain; 55 patients received a permanent implant. At 12-month visit, 71% of patients sustained a ≥50% pain improvement; 24.5% experienced an ≥80% pain improvement.	79% reduction in disability	42% reduced or discontinued opioid usage. Clinical benefits at 12 months maintained through 18 months.	Post SCS implant, 10 patients reported a device-related event (infection, lead migration, persistent pain at IPG, damage to the IPG).
3×3 crossover design without washout					Burst	SCS	Sham	
Schu et al (2014)[46]	FBSS	• Burst stimulation • SCS • No stimulation (sham-control)	N=20 n=20	1 wk (burst vs. SCS vs. sham)[a]				No SAEs reported
				• Mean NRS pain intensity scores, favoring burst	4.7	7.1	8.3	
				• Mean SF-MPQ pain quality scores, favoring burst	19.5	28.6	33.5	

Study	Population	Interventions	N at Baseline and FU	Results				Complications
				• Mean ODI scores, favoring burst	19.8	24.6	29.5	
De Ridder et al (2013)[44,]	Neuropathic limb pain	• Burst stimulation • SCS • No stimulation (sham-control)	N=15 n=15	1 wk (burst vs. SCS vs. sham)[a]				Not reported
				• Mean improvement in VAS scores ○ Back pain	3.8	2.2	1.4	
				• ○ Limb pain	3.9	3.9	0.9	
2×2 crossover								
De Ridder et al (2010)[45,]	Neuropathic pain	• Burst stimulation • SCS	N=12 n=unclear	Two 1-h sessions (burst vs. SCS)[b]				Not reported
				• Mean improvement in VAS scores ○ Axial pain	5.3	1.8		
				• ○ Limb pain	7.3	4.4		
				• Improvement in SF-MPQ sensory scores	16.7	8.6		
				• Improvement in SF-MPQ affective scores	6.7	4.3		
Deer et al (2018)[48,]	Chronic intractable pain of the trunk and/or limbs	• Burst stimulation • SCS	N=100	12 wk (burst vs. SCS)				2 study-related SAEs (persistent pain and/or numbness

Study	Population	Interventions	N at Baseline and FU	Results				Complications
								and 1 unsuccessful lead placement); 21 SAEs in total; 158 total adverse events in 67 patients
				• Mean VAS scores at end of period, favoring burst	Diff = -5.1 mm (noninferiority) p<.001			
				• Responder (≥30% improvement in VAS score)	60%	51%		
Hara et al (2022)[50,]	Chronic radicular pain after lumbar spine surgery	• Burst stimulation • Sham stimulation	N=50; n=47 included in analysis	3 mo				9 patients experienced adverse events
				• Mean change in ODI	-11		-9	
5×5 crossover					Diff=-1.3; p=.32			
Kriek et al (2017)[47,]	CRPS	• Burst stimulation • SCS 40 Hz • SCS 500 Hz • SCS 1200 Hz • No stimulation (sham-control)	N=33 n=29	2 wk (burst vs. SCS at 40, 500, and 1200 Hz vs. sham)				No SAEs reported; 3 electrodes became dislodged; 2 patients reported itching
				• Mean VAS scores at end of period	48	40[c]	64	

Study	Population	Interventions	N at Baseline and FU	Results				Complications
				• Mean global perceived effect (7-point scale where 7 [very satisfied] to 1 [not at all satisfied])	4.7	5.3[c]	3.5	
3×3 crossover design with washout								
Eldabe et al (2020)[49,]	Chronic back and leg pain	• Burst stimulation • SCS 500 Hz • Sham	N=19 n=16	2 wk treatment phase (burst vs. SCS at 500 Hz vs. sham); each treatment phase included a washout of 9 days				Increased pain was the most commonly reported adverse event at each treatment phase
				• Pain intensity: geometric mean pain VAS	5.4	3.8	5.1	
Parallel design								
Deer et al (2023)[51,]	Chronic low back pain in patients who had not undergone and were not candidates for lumbar spine surgery	• Burst stimulation • CMM	N=269 n=183 at 6 mo		Burst	CMM		

Study	Population	Interventions	N at Baseline and FU	Results				Complications
				Responder: 50% reduction in NRS	73%	7%		3 serious and 14 non–serious device- or procedure-related events

CMM: conventional medical management; CRPS: complex regional pain syndrome; Diff: difference; FBSS: failed back surgery syndrome; FU: follow-up; IPG: implantable pulse generator; NRS: numeric rating scale; ODI: Oswestry Disability Index; SAE: serious adverse events; SCS: spinal cord stimulation; SF-MPQ: Short-Form McGill Pain Questionnaire; VAS: visual analog scale; RCT: randomized controlled trial.
[a] Analyses do not appear to take into account properly the crossover design; therefore, p values are not reported here.
[b] Statistical treatment comparisons not provided.
[c] Results from SCS 40 Hz reported here. Three different levels of SCS were given. Similar results were reported for the other 2 SCS levels and are not shown in this table.

Section Summary: Standard Spinal Cord Stimulation for Refractory Chronic Trunk or Limb Pain

The evidence on the efficacy of standard spinal cord stimulation for the treatment of chronic limb or trunk pain consists of a number of systematic reviews and RCTs evaluating patients with refractory pain due to failed back surgery syndrome, CRPS , or diabetic neuropathy. RCTs were heterogeneous regarding patient populations and participants were unblinded (no trials used sham surgeries or devices) but they consistently reported reductions in pain, with clinically and statistically significant effect sizes and reductions in medication use for at least 6 months. Even with a sham-controlled surgery or device, blinded outcomes assessment may not be feasible for spinal cord stimulation because active spinal cord stimulation is associated with paresthesias. Given the extensive treatment effects with consistent findings across studies, this evidence suggests that spinal cord stimulation is a reasonable treatment option.

The evidence for standard spinal cord stimulation with burst stimulation has been evaluated in 6 crossover RCTs. Five of the RCTs had fewer than 35 patients. Inferences drawn from these trials are limited by small sample sizes, short follow-up, and flawed statistical analyses. The largest RCT (SUNBURST) was a 12-week, multicenter, randomized, unblinded, crossover, noninferiority trial assessing traditional spinal cord stimulation or burst stimulation in 100 patients with chronic pain of the trunk and/or limbs. The burst was noninferior to spinal cord stimulation for overall VAS score (at 12 weeks). The proportion of patients whose global impression was improved (minimally, moderately, or very much improved) was approximately 74% in both groups. Seventy-eight percent of patients reported being satisfied with both spinal cord stimulation and burst at the end of the 24-week crossover portion of the trial, while 7% were satisfied with spinal cord stimulation but not burst and 10% were satisfied with burst but not spinal cord stimulation. However, more patients (70.8%) reported preferring burst stimulation over spinal cord stimulation after the 24-week crossover.

HIGH-FREQUENCY SPINAL CORD STIMULATION FOR REFRACTORY CHRONIC TRUNK OR LIMB PAIN

Clinical Context and Therapy Purpose

The purpose of high-frequency SCS in individuals who have treatment-refractory chronic trunk or limb pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with treatment-refractory chronic pain of the trunk or limbs. Examples of treatment-refractory chronic pain include failed back surgery syndrome, CRPS (ie, reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy.

Interventions

The therapy being considered is high-frequency SCS. High-frequency SCS devices use a higher frequency (10000 Hz) compared with the standard SCS devices. High-frequency SCS potentially lowers the incidence of paresthesias compared with standard SCS.

Comparators

The following practice is currently being used to treat patients with treatment-refractory chronic pain of the trunk or limbs: standard SCS, medical therapy, or surgical therapy.

Outcomes

The IMMPACT group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[2,] The IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (Table 2).[3,4,]

Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration, failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

Sun et al (2024) conducted a meta-analysis of 7 RCTs (published through 2023) aimed to systematically evaluate the efficacy and safety of high-frequency SCS in managing chronic pain.[52,] The results demonstrated that high-frequency SCS had superior long-term efficacy in chronic pain treatment compared to the control group (relative risk [RR] = 2.44, 95% CI: 1.20 to 4.96, p=0.01), showing a significant improvement in the ODI score (MD=3.77, 95% CI: 1.17 to 6.38, p=0.005). However, high-frequency SCS did not exhibit statistically significant effects in pain assessment (standardized mean difference [SMD] = -0.59, 95% CI: -1.28 to 0.10, p=0.09), PGI score, Clinical Global Impression of Improvement (CGI-I) score, and occurrence of adverse effects.

Bicket et al (2016) published a systematic review of controlled trials on high-frequency SCS.[53,] Reviewers searched for RCTs and controlled nonrandomized studies of adults with pain for at least 3 months who were treated with high-frequency SCS (ie, ≥1000 Hz) and prospectively assessed pain outcomes. Eight studies met these inclusion criteria: 2 RCTs (detailed below) and 6 controlled nonrandomized studies. Both RCTs and 5 of 6 controlled studies addressed low back pain; the remaining controlled study addressed migraine. Reviewers used the Cochrane criteria to rate bias in the RCTs. One trial (Perruchoud et al [2013][54,]) was not rated as having a high-risk of bias in any domain, and the other (Kapural et al [2015][55,]) was rated as having a high-risk of bias in the domain of performance and detection bias because it was unblinded. Studies were reviewed qualitatively (ie, study findings were not pooled).

Randomized Controlled Trials

Six RCTs addressed high-frequency SCS (Table 5): Perruchoud et al (2013)[54,] compared high-frequency SCS (5000 Hz) with sham control in a crossover design (N=40), Petersen et al (2021)[56,] compared high-frequency SCS plus medical management with medical management alone, while Kapural et al (2015)(N=198)[55,], Bolash et al (2019) (N=99)[57,], and De Andres et al (2017)(N=60)[58,] compared high-frequency SCS (10,000 Hz) with standard SCS. All 6 trials are summarized in Table 5. The trials with N>100 are described individually.

Petersen et al (2021)[56,] randomized 216 participants with painful diabetic neuropathy (baseline lower limb VAS ≥5 cm on a 10 cm scale) refractory to prior pharmacological treatment to high-frequency SCS plus conventional medical management (n=113) versus conventional medical management alone (n=103). All participants were randomized to high-frequency SCS and underwent a trial stimulation period. Participants were eligible for permanent implantation of the stimulation device if at least 50% pain relief was achieved during the trial period. Participants remained in their randomized groups for 6 months, after which time they were eligible to crossover to the other group in the event of inadequate pain relief. The addition of high-frequency SCS to conventional medical management was associated with significantly improved pain scores at 6 month follow-up (Table 5). Results from 12-month follow-up were consistent in finding a significant pain benefit for high-frequency SCS plus medical management versus medical management alone.[59,] Limitations of the study include a lack of blinding for participants and investigators.

Kapural et al (2015, 2016)[55,60,] included 198 patients with chronic leg and back pain who had received conventional medical management but not SCS. Kapural et al (2015) included an active, but unblinded, comparator (standard SCS) and included a trial SCS period up to 2 weeks post-randomization after which only responders continued with stimulation. Outcomes were reported

after 3, 12, and 24 months of treatment. The response in the standard SCS group was similar to previous SCS trials, between 45% and 50% for back pain and 50% to 55% for leg pain at 3, 12, and 24 months. The response was clinically and statistically significantly higher with high-frequency SCS than with SCS for both back (range, »75% to 85%) and leg pain (range, »70% to 85%) at all time points. A limitation of the Kapural et al (2015, 2016) trial was that nonresponders during the stimulation trial period were excluded from statistical analysis. Instead, assuming patients who were not implanted were nonresponders corresponds to response rates at 3 months of about 75% in high-frequency SCS and 37% in SCS for back pain and 74% and 46% for leg pain (calculated, data not shown).

Kapural et al (2022)[61,] enrolled 159 individuals with nonsurgical refractory back pain, defined as patients with chronic back pain refractory to conventional medical management (CMM) who have no history of spine surgery and are not acceptable candidates for spine surgery, who were randomized in a 1:1 ratio to CMM with and without high-frequency (10-kHz) SCS from September 2018 to January 2020. CMM was generally consistent with clinical guidelines. Participants randomized to high-frequency SCS received trial stimulation of up to 14 days. Follow-up visits were completed at 1, 3, 6, 9, and 12 months. The median age was between 53 and 58 years and median time from diagnosis was 8 years. Eighty-one percent of CMM plus high-frequency SCS participants versus 1% of CMM participants were responders (primary outcome, ≥ 50% pain relief) at 3 months (p<.001) and 80% versus 3% were responders at 6 months (p<.001). The study was not blinded and nonresponders during the stimulation period were excluded from further analysis.

Table 5. Characteristics and Result of RCTs of Using High-Frequency Spinal Cord Stimulation

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				Outcome Measure	*Int*	*Ctrl*	*p*	
Perruchoud et al (2013)[54,]	Chronic low back pain radiating in 1 or both legs; previously treated with SCS	• HFSCS • Sham • 2×2 crossover design with conventional SCS before both arms	N=40 n=33	2 wk (HFSCS vs. sham)				One patient had malaise attributed to a vasovagal attack
				• Responder (at least minimal improvement on patient-reported global impression of change)	42%	30%	.30	

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				• VAS score	4.35	4.26	.82	
				• Health utility	0.48	0.46	.78	
Petersen et al (2021)[56]; Petersen et al (2022)[62]; Petersen et al (2023)[63]	Painful diabetic neuropathy	• HFSCS + medical management • Medical management	N=216 n at 6 mo=187	6 mo (HFSCS + medical management vs. medical management)				• SAEs, 12% vs. 0% • Wound complications (dehiscence, impaired healing, or infection): 6% vs. 0%
•				• Responder (proportion with ≥50% change in VAS without a meaningful worsening of baseline neurological deficits)	86%	5%	<.0001	
				• Remitter (proportion with pain VAS ≤3 cm for 6 consecutive months)	60%	1%	<.001	
				• Quality of life (EQ-5D-5L Index, mean change from baseline)	0.130 (SD 0.159)	-0.031 (SD 0.127)	<.001	
		Originally assigned to HFSCS and crossovers to HFSCS combined	n=104 HFSCS and n=77 crossovers to HFSCS	12 mo (HFSCS + crossovers to HFSCS)				

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				• Responder (proportion with ≥50% change in VAS)	85%			
				• Quality of life (EQ-5D-5L Index, mean change from baseline)	0.14 (95 % CI, 0.10 to 0.17)			
			n=142 HFSCS and crossovers	• Responder (proportion with ≥50% change in VAS)	90%			
Kapural et al (2015, 2016)[55,60],	Chronic back and leg pain	• HFSCS • SCS	N=198 n at 3 mo=171 n at 24 mo=156	3 mo (HFSCS vs. SCS)				• Stimulation discomfort, 0% vs. 47% • No stimulated-rated SAEs or neurologic deficits
•				• Responder (≥50% back pain reduction with no stimulation-related neurologic deficit): ○ Back pain	85%	44%	<.001	
				• ○ Leg pain	83%	55%	<.001	
			n at 12 mo=171	12 mo (HFSCS vs. SCS)				
				• Responders ○ Back pain	80%	50%	NR	
				•	80%	56%	NR	

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				○ Leg pain				
				• Decreased opioid use	36%	26%	.41	
				• Improvement in ODI score	16.5	13.0	NR	
				24 mo (HFSCS vs. SCS)				
				• Responders ○ Back pain	77%	49%	<.001	
				○ Leg pain	73%	49%	<.001	
De Andes et al (2017)[58,]	FBSS	• HFSCS • SCS	N=60 n=55 analyzed	12 mo (HFSCS vs. SCS)				
				Responder (≥50% in pain intensity in NRS score at 12 mo)[a]	NR	NR		
				Improvement in NRS score	6.1	5.9	.56	
				Improvement in ODI score	23.0	22.1	.96	
Bolash et al (2019)[57,]	FBSS	• HFSCS SCS	N=99 n=72 analyzed	6 mo (HFSCS vs SCS)				
				Responder (≥50% reduction VAS for back pain)	92%	82%	Noninferiority <.001	
				Remission (VAS for back pain of ≤25 mm)	84%	47%		
Kapural et al (2022); Patel et al (2023)[61,64,]	Nonsurgical refractory back pain	• HFSCS + medical management • Medical management	N=159 n=143 analyzed	3 mo (HFSCS+medical management vs medical management)				

Study	Population	Interventions	N at Baseline and Follow-Up	Results				Complications
				Responder (≥ 50% pain relief)	81%	1%	<.001	
				Mean change in EQ-5D-5L score (SD)	0.21 (0.14)	0.004 (0.02)	<.001	
			n=140	6 mo (HFSCS+medical management vs medical management)				
				Responder (≥ 50% pain relief)	80%	3%	<.001	
				Mean change in EQ-5D-5L score (SD)	0.21 (0.13)	-0.04 (0.14)	<.001	
			n=98	24 mo (HFSCS only)				
				Responder (≥ 50% pain relief)	82%			
				Mean change in EQ-5D-5L score	0.19 (NR)			

Ctrl: control; EQ-5D-5L: EuroQol 5-Dimension Questionnaire; FBSS: failed back surgery syndrome; HFSCS: high-frequency spinal cord stimulation; Int: intervention; NR: not reported; NRS: numeric rating scale; ODI: Oswestry Disability Index; SAE: serious adverse events; SCS: spinal cord stimulation; VAS: visual analog scale; RCT: randomized controlled trial.

[a] Despite the responder criteria being stated to be the primary outcome, the results for this outcome were not reported.

Section Summary: High-Frequency Spinal Cord Stimulation for Refractory Chronic Trunk or Limb Pain

The evidence for high-frequency SCS compared with standard SCS consists of two systematic reviews, and RCTs. Two RCTs that enrolled participants not previously treated with SCS reported clinically and statistically significant benefits associated with high-frequency SCS. A crossover RCT enrolling patients with pain despite previous treatment with SCS reported no difference between high-frequency SCS and sham stimulation. However, interpretation of this trial is limited due to the significant period effect.

DORSAL ROOT GANGLION STIMULATION FOR REFRACTORY CHRONIC TRUNK OR LIMB PAIN

Clinical Context and Therapy Purpose

The purpose of dorsal root ganglion stimulation (DRGS) in individuals who have treatment-refractory chronic trunk or limb pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with treatment-refractory chronic pain of the trunk or limbs. Examples of treatment-refractory chronic pain include FBSS, CRPS (ie, reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy, and painful diabetic neuropathy.

Interventions

The therapy being considered is DRGS. Dorsal root ganglion uses the same epidural approach technique as SCS but targets a different anatomical 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.

Comparators

The following practice is currently being used to treat patients with treatment-refractory chronic pain of the trunk or limbs: standard SCS, medical therapy, or surgical therapy.

Outcomes

The IMMPACT group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[2,] The IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (Table 2).[3,4,]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

DORSAL ROOT GANGLION IMPLANTED DEVICE

Systematic Reviews

Campos-Fajardo et al (2024) conducted a qualitative systematic review to evaluate the efficacy of DRGS in the management of chronic pain.[65,] The review included 29 articles published between 2018 and 2024, covering a range of patient diagnoses extending beyond CRPS. The majority of these studies were observational (21), supplemented by 5 clinical trials, 1 secondary analysis, and 2 pilot studies. This systematic review confirmed the effectiveness of DRGS therapy in managing various chronic pain conditions. It highlighted significant improvements in patients' quality of life, functionality, and mood states, positioning DRGS as a viable alternative for those who have not responded to traditional treatments.

Mattie et al (2024) conducted a qualitative systematic review of 6 RCTs that showed significant pain reduction in CRPS patients treated with SCS and DRGS.[66,]Preference for specific SCS settings varied among patients, with no clear superiority of one setting over another. Innovations in SCS technology, including novel waveforms and frequencies, demonstrated potential for enhanced efficacy and patient comfort.

Several systematic reviews of DRGS devices have been published: Vuka et al (2019)[67,], Deer et al (2020)[68,], Monan et al (2021)[69,], and D'Souza et al (2022).[70,] The reviews all include one RCT (ACCURATE) and several observational studies. The RCT is described in the following section.

Randomized Controlled Trial

The ACCURATE study (NCT01923285) compared DRGS with standard SCS.[71,72,] As reported by Deer et al (2017), eligibility criteria for this multicenter, unblinded, noninferiority trial included chronic (≥6 months) intractable (failed ≥2 drugs from different classes) neuropathic pain of the lower limbs associated with a diagnosis of CRPS or causalgia and no previous neurostimulation. Patients were randomized to DRGS with the Axium device or standard SCS. Patients first underwent a temporary trial of stimulation lasting 3 to 30 days, depending on the protocol at each site. Patients who had a 50% or greater reduction in lower limb pain after the temporary trial were eligible for permanent stimulation. Those who failed temporary stimulation exited the trial but were included in the analysis as treatment failures. Trial characteristics are shown in Table 6.

A total of 152 patients were randomized, and 115 (n=61 DRGS , n=54 SCS) had a successful temporary trial and continued to permanent implantation. The primary outcome was a composite measure of treatment success. Success was defined as (1) a 50% or greater reduction in VAS score and (2) no stimulation-related neurologic deficits. The noninferiority margin was set at 10%. Results are shown in Table 7. No patients experienced neurologic deficits in either group. Regarding paresthesias, at 3 months and 12 months, SCS patients were significantly more likely to report paresthesias in nonpainful areas than DRGS patients. At 3 months, 84.7% of DRGS patients and 65% of SCS patients reported paresthesias only in their painful areas; at 12 months, these percentages were 94.5% and 61.2%, respectively. Limitations in study relevance, design, and conduct are shown in Tables 8 and 9.

Mekhail et al (2019) conducted a sub-analysis on the patients receiving DRGS in the ACCURATE study, to evaluate the occurrence and risk factors for paresthesia.[73,] Among the 61 patients with dorsal root ganglion implants, the rates of paresthesia at 1 month, 3 months, 6 months, 9 months, and 12 months were 84%, 84%, 66%, 62%, and 62%, respectively. The patients who were paresthesia-free reported similar or better outcomes for pain and quality of life. Risk factors

for paresthesia occurrence included higher stimulation amplitudes and frequencies, number of implanted leads, and younger age.

Table 6. RCT Characteristics of DRG Implanted Devices

					Interventions	
Study	**Countries**	**Sites**	**Dates**	**Participants**	DRG	SCS
Deer et al (2017)[71]; ACCURATE (NCT01923285)	U.S.	22	2013-2016	• CRPS or causal lower extremities • Chronic pain (6 mo) • Stimulation-naïve • Failed ≥2 pharmacologic treatments	AXIUM Neurostimulator System (n=76)	RestoreUltra and RestoreSensor (n=76)

ACCURATE: A Prospective, Randomized, Multi-Center, Controlled Clinical Trial to Assess the Safety and Efficacy of the Spinal Modulation™ AXIUM™ Neurostimulator System in the Treatment of Chronic Pain; CRPS: complex regional pain syndrome; DRG: dorsal root ganglion; RCT: randomized controlled trial; SCS: spinal cord stimulation.

Table 7. RCT Results of DRG Implanted Devices

Study	**≥50% Reduction in VAS Scores for Pain**	**Physical Functioning**	**Emotional Functioning**	**Quality of Life**		**Safety**
		Mean BPI Interference	*POMS Total Score*	*SF-36 PCS*	*SF-36 MCS*	*SAEs*
Deer et al (2017)[71]						
At 3 months						
n	139	113	NR	113	113	NR
DRG	81%	4.2	NR	11.8	8.3	
SCS	56%	3.0	NR	9.4	4.8	
TE (95% CI) (p)	NR (noninferiority p<.001; superiority p<.001)	1.1 (0.2 to 2.1) (<.05 favoring DRG)	NR (.04 favoring DRG)	2.5 (-0.7 to 5.7)	3.5 (-0.5 to 7.5)	
At 12 months						
n	132	105	NR	105	105	152
DRG	74%	3.9	»18	11.5	6.2	11%
SCS	53%	2.6	»8	8.0	3.6	15%
TE (95% CI) (p)	NR (noninferiority p<.001; superiority p<.001)	1.3 (0.2 to 2.3)(<.05 favoring DRG)	NR (<.001)	3.5 (-0.1 to 7.1)(.04 favoring DRG)	2.6 (-1.9 to 7.1)	NR (.62)

BPI: Brief Pain Inventory; CI: confidence interval; DRG: dorsal root ganglion; MCS: Mental Component Summary; NR: not reported; POMS: Profile of Mood States; PCS: Physical Component Summary; RCT: randomized controlled trial; SAE: serious adverse event; SCS: spinal cord stimulation; SF-36: 36-Item Short-Form Health Survey; TE: treatment effect; VAS: visual analog scale.

Table 8. Study Relevance Limitations for RCTs of DRG Implanted Devices

Study	Population	Intervention	Comparator	Outcomes	Follow-Up
Deer et al (2017)[71]					

DRG: dorsal root ganglion; RCT: randomized controlled trial.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations for RCTs of DRG Implanted Devices

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power	Statistical
Deer et al (2017)[71]		1, 2. Patients and study staff not blinded. Outcomes mostly patient reported which could lead to bias. However, an active control (SCS) was used.				4. Treatment effects not reported for some outcomes but p values reported.

DRG: dorsal root ganglion; RCT: randomized controlled trial; SCS: spinal cord stimulation.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2.

Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

Because RCT data are available for DRGS, observational studies are discussed if they add information not available from the RCTs (eg, longer follow-up including adverse events, data on an important subgroup, etc). Deer et al (2019) compared the safety and complaint records from the manufacturers of DRGS (n=500+) and SCS (n=2000+) devices, from April 2016 through March 2018.[74,] The overall safety event rate for the study timeframe was 3.2% for DRGS and 3.1% for SCS. Persistent pain was reported at a rate of 0.2% by patients with dorsal root ganglion implants and 0.6% by patients with SCS implants. Infection rates were 1.1% in both groups of patients. Cerebrospinal leaks were reported in 0.5% of patients with DRGS implants and in 0.3% of patients with SCS implants.

A retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of DRGS.[75,] The MAUDE database was queried for DRGS 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.

DORSAL ROOT GANGLION WIRELESS INJECTABLE DEVICE

Case Series

A case series, which included 11 patients, was published by Weiner et al (2016).[76,] This study included patients with FBSS who had chronic intractable neuropathic pain of the trunk and/or lower limbs. Five patients participated in phase 1 of the study (device not anchored), and 6 additional patients participated in phase 2 (device anchored). During phase 1, the device migrated more than was recommended and thus it was anchored in the remaining patients. Baseline VAS scores were 5 or higher in all patients. Seven (63%) of the 11 patients reported good to excellent overall pain relief (VAS score reduction, ≥50%), 2 patients reported fair overall intensity pain relief (25% to 50% reduction), and 2 patients reported poor or no overall pain relief (0% to 25%). No adverse events were reported.

Section Summary: Dorsal Root Ganglion Stimulators for Refractory Chronic Trunk or Limb Pain

Systematic reviews, 1 unblinded RCT, and case series have evaluated DRGS in patients with chronic trunk and/or limb pain. The RCT (N=152) found that patients receiving DRGS 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 SCS devices. In addition, DRGS was found to be noninferior to SCS 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 DRGS group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Patients in the DRGS group

also reported more improvement in interference with physical functioning and mood states. Rates of serious adverse events were similar.

SPINAL CORD STIMULATION FOR CRITICAL LIMB ISCHEMIA

Clinical Context and Therapy Purpose

The purpose of SCS in individuals who have critical limb ischemia is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with critical limb ischemia. Critical limb ischemia is described as pain at rest or the presence of ischemic limb lesions.

Interventions

The therapy being considered is SCS. SCS uses low-level epidural electrical stimulation of the spinal cord dorsal columns. Its mechanism of action is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits. SCS devices consist of several components: (1) the lead delivering 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. The lead may incorporate 4 to 8 electrodes, depending on the complexity of the pain pattern. A trial period in which the electrode is temporarily implanted in the epidural space is recommended, prior to the permanent implantation. Most SCS devices operate under a frequency of 100 to 1000 Hz.

If patients are not suitable candidates for limb revascularization (typically due to insufficient distal runoff), amputation may be required. SCS has been investigated in this subset of patients as a technique to relieve pain and decrease the incidence of amputation.

Comparators

The following practice is currently being used to treat patients with critical limb ischemia: medical therapy or surgical therapy (revascularization surgery or amputation).

Outcomes

The IMMPACT group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[2,] The IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (Table 2).[3,4,]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

An updated Cochrane review by Ubbink and Vermeulen (2013) assessed the use of SCS in peripheral vascular diseases.[77,] Reviewers included RCTs and non-RCTs evaluating the efficacy of SCS in adults with non-reconstructable, chronic critical leg ischemia. Six trials were identified; all were conducted in Europe and 5 were single-country studies. SCS was compared with other nonsurgical interventions. One study was not randomized, and none were blinded. In a pooled analysis of data from all 6 studies, there was a significantly higher rate of limb survival in the spinal cord stimulation group than in the control group at 12 months (relative risk [RR], 0.75; 95% CI, 0.57 to 0.95;absolute risk difference, -0.11; 95% CI, -0.20 to -0.02). The 11% difference in the rate of limb salvage means that 9 patients would need to be treated to prevent 1 additional amputation (95% CI, 5 to 50 patients). However, when the nonrandomized study was excluded, the difference in the rate of amputation no longer differed significantly between groups (RR, 0.78; 95% CI, 0.58 to 1.04; absolute risk difference, -0.09; 95% CI, -0.19 to 0.01). The SCS patients required significantly fewer analgesics, and more patients reached Fontaine stage II (intermittent claudication) than in the control group. There was no difference in ulcer healing (but only 2 studies were included in this analysis). In the 6 trials, 31 (15%) of 210 patients had a change in stimulation requiring intervention, 8 (4%) experienced the end of battery life, and 6 (3%) infections required device removal.

Previously, Klomp et al (2009) published a meta-analysis of RCTs that used SCS to treat patients with critical limb ischemia.[78,] The same 5 RCTs identified in the Cochrane review were included. Reviewers did not find a statistically significant difference in the rate of amputation in the treatment or control groups. The RR of amputation was 0.79 (95% CI, 0.59 to 1.06), with a risk difference of -0.07 (95% CI, -0.17 to 0.03). Reviewers also conducted additional analyses of data from their 1999 RCT to identify factors associated with better or worse prognoses.[79,] They found that patients with ischemic skin lesions had a higher risk of amputation than patients with other risk factors. There were no significant interactions between this and any other prognostic factor. The analyses did not identify subgroups of patients who might benefit from SCS.

A systematic review of non-revascularization-based treatments by Abu Dabrh et al (2015) for patients with critical limb ischemia included SCS as 1 of the treatments. The review identified 5 RCTs for inclusion.[80,] In the pooled analysis, reviewers found that SCS was associated with reduced risk of amputation (odds ratio [OR], 0.53; 95% CI, 0.36 to 0.79); risk difference was not reported.

Section Summary: Critical Limb Ischemia

Five relatively small RCTs comparing SCS with usual care have assessed patients with critical limb ischemia. In pooled analyses from 3 systematic reviews, SCS was associated with a lower risk of amputation versus control, but results were not consistently statistically significant due to differences in methodologies. This evidence is not sufficient to determine whether SCS would improve outcomes for patients with critical limb ischemia.

SPINAL CORD STIMULATION FOR SELECTED OTHER MEDICAL CONDITIONS

Clinical Context and Therapy Purpose

The purpose of SCS in individuals who have other medical conditions (eg, angina pectoris, heart failure, or cancer-related pain) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with treatment-refractory angina pectoris, heart failure, or cancer-related pain.

Interventions

The therapy being considered is SCS. SCS uses low-level epidural electrical stimulation of the spinal cord dorsal columns. Its mechanism of action is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits. SCS devices consist of several components: (1) the lead delivering 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. The lead may incorporate 4 to 8 electrodes, depending on the complexity of the pain pattern. A trial period in which the electrode is temporarily implanted in the epidural space is recommended, prior to the permanent implantation. Most SCS devices operate under a frequency of 100 to 1000 Hz.

Comparators

The following practice is currently being used to treat patients with

- refractory angina pectoris: medical therapy or coronary revascularization.
- heart failure: medical therapy or coronary revascularization.
- cancer-related pain: medical therapy.

Outcomes

The IMMPACT group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[2,] The IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (Table 2).[3,4,]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

REFRACTORY ANGINA PECTORIS

Systematic Reviews

Pan et al (2017) identified 12 RCTs that evaluated SCS versus control in patients with refractory angina pectoris.[81,] Most studies had small sample sizes (i.e., <50 patients; N=476). Follow-up ranged widely from 2 weeks to 12 months, and control interventions were not well described in the systematic review. The included studies were generally assessed to have low risk of bias.. Pooled analyses favored the spinal cord stimulation group for most outcomes (e.g., for exercise time after the intervention, pain level [VAS score], angina frequency), but there were no significant differences between intervention and control groups for physical limitation or angina stability.

Another systematic review was published by Tsigaridas et al (2015).[82,] It included 9 RCTs evaluating SCS for refractory angina: 7 compared SCS with low or no stimulation and 2 compared SCS with alternative medical or surgical therapy for angina. Reviewers found that most RCTs were small and variable in quality based on modified Jadad criteria. Reviewers reported: "2 of the RCTs were of high quality (Jadad score 4); 2 were of low quality (Jadad score 1), and the remaining ones were of intermediate quality (Jadad score 2 to 3)." Most trials comparing SCS with low or no stimulation found improvements in outcomes with SCS; however, given limitations in the evidence base, reviewers concluded that larger multicenter RCTs would be needed to assess the efficacy of SCS for angina.

Randomized Controlled Trials

Two of the largest RCTs included in the systematic reviews were Zipes et al (2012)[83,] and Lanza et al (2011).[84,]

Zipes et al (2012) published an industry-sponsored, single-blind, multicenter trial with sites in the US and Canada.[83,] This trial was terminated early because interim analysis by the data and safety monitoring board found the treatment futile. A total of 118 patients with severe angina, despite maximal medical treatment, were enrolled. Of the 118 patients, 71 (60%) underwent SCS implantation with the Intrel III neurostimulator (Medtronic). The remaining 47 patients did not meet eligibility criteria post-enrollment or had other issues (eg, withdrew consent). The investigators had originally been planning to randomize up to 310 patients but enrollment was slow. Implantation was successful in 68 patients; this group was randomized to high-stimulation (n=32) or a low-stimulation control (n=36). The low-stimulation control was designed so that patients would feel paresthesia but the effect of stimulation would be subtherapeutic. The primary outcome was a composite of major adverse cardiac events, which included death from any cause, acute myocardial infarction, or revascularization through 6 months. Fifty-eight (85%) of 68 patients contributed data to the 6-month analysis; analysis was by intention-to-treat. The proportion of patients experiencing major adverse cardiac events at 6 months did not differ significantly between groups (12.6% in the high-stimulation group vs. 14.6% in the low-stimulation group; p=.81). The trial sample size was small, and it might have been underpowered for clinically meaningful differences.

A controlled trial from Italy by Lanza et al (2011) randomized 25 patients to 1 of 3 treatment groups: SCS with standard stimulation (n=10), SCS with low-level stimulation (75% to 80% of

the sensory threshold) (n=7), or very low-intensity SCS (n=8).[84,] Thus, patients in groups 2 and 3 were unable to feel sensation during stimulation. After a protocol adjustment at 1 month, patients in the very low-intensity group were re-randomized to 1 of the other groups of which there were 13 patients in the standard stimulation group and 12 patients in the low-level stimulation group. At the 3-month follow-up (2 months after re-randomization), there were statistically significant between-group differences in 1 of 12 outcome variables. There was a median of 22 angina episodes in the standard stimulation group and 10 in the low-level stimulation group (p=.002). Nonsignificant variables included the use of nitroglycerin, quality of life, VAS score, Canadian Cardiovascular Society angina class, exercise-induced angina, and scores on 5 subscales of the Seattle Angina Questionnaire.

Uncontrolled studies

Because RCT data are available for SCS, uncontrolled studies are discussed if they add information not available from the RCTs (eg, longer follow-up including adverse events, data on an important subgroup, etc). Lanza et al (2012) reviewed observational studies on SCS in patients with refractory angina pectoris.[85,] They identified 16 studies (N=1204 patients) but noted that patients might have been included in more than 1 report. The most frequently reported complications were lead issues (ie, electrode dislodgement or fracture requiring repositioning) or internal programmable generator failure during substitution. Lead issues were reported by 10 studies (N=450 patients). In these studies, 55 cases of lead or internal programmable generator failure were reported. No fatalities related to SCS treatment were reported.

Section Summary: Refractory Angina Pectoris

Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some studies have reported benefits, most have not. In 2 more recent RCTs, there were no significant benefits for the primary outcomes. Overall, this evidence is mixed and insufficient to permit conclusions on whether health outcomes are improved.

HEART FAILURE

Systematic Reviews

Ashrafpour (2024) conducted a systematic review to investigate the efficacy of SCS as an adjunctive therapy in heart failure. 4 studies (2 RCTs and 2 pilot studies) with a total of 125 patients were selected.[86,]Participants had heart failure with NYHA classification ranging from 2 to 3. Primary endpoints included heart failure-related symptoms, left ventricular ejection function, VO2 max, and NT-proBNP (N-terminal Pro-Brain Natriuretic Peptide). The studies demonstrated the safety and feasibility of SCS therapy, although outcomes varied. Two studies reported improvements in New York Heart Association classification, Minnesota Living with Heart Failure Questionnaire (MLHFQ), and quality of life parameters, while only one study showed positive changes in Left Ventricular Ejection Fraction and VO2 max. No studies found significant changes in NT-proBNP following SCS therapy. Discrepancies in results could be due to methodological variations and induction technique diversity. Further studies are needed to develop a solid approach for employing SCS in heart failure patients.

Section Summary: Heart Failure

A 2024 systematic review was conducted to investigate the efficacy of SCS as an adjunctive therapy in heart failure. Four studies (including 2 RCTs) with a total of 125 patients were

selected. Two studies reported improvements in New York Heart Association classification, and quality of life parameters, while only one study showed positive changes in left ventricular ejection function and VO2 max. No studies found significant changes in NT-proBNP (N-terminal Pro-Brain Natriuretic Peptide) following SCS therapy. Discrepancies in results could be due to methodological variations and induction technique diversity. Further studies are needed to develop a solid approach for employing SCS in heart failure patients.

CANCER-RELATED PAIN

Systematic Reviews

A Cochrane review by Lihua et al (2013) assessed SCS for the treatment of cancer-related pain in adults.[87,] Reviewers did not identify any RCTs evaluating the efficacy of SCS in this population. Four case series using a before-after design (N=92 patients) were identified. Peng et al (2015) updated this review, finding no new studies meeting inclusion criteria identified.[88,] They concluded: "Current evidence is insufficient to establish the role of spinal cord stimulation in treating refractory cancer-related pain."

Section Summary: Cancer-Related Pain

A Cochrane review did not identify any RCTs evaluating SCS for the treatment of cancer-related pain.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinology

In 2022, the American Association of Clinical Endocrinology published evidence-based recommendations for the care of individuals with diabetes mellitus.[89,]. The guidelines state that 'Neuromodulatory techniques such as HFSCS [high-frequency SCS] and combining pharmacological with nonpharmacological approaches should be considered in those with refractory painful DPN [diabetic peripheral neuropathy]'. The evidence for the statement was rated as Grade B [Strong]; BEL[best evidence level] 1 [Randomized controlled trial; Meta-analysis of only randomized controlled trials].

American Society of Regional Anesthesia and Pain Medicine

In 2023, American Society of Regional Anesthesia and Pain Medicine published evidence-based consensus guidelines on patient selection and trial stimulation for SCS therapy for chronic non-cancer pain.[90,]Recommendations included that SCS trial should be performed before a definitive SCS implant except in anginal pain (grade B). All patients must be screened with an objective validated instrument for psychosocial factors, and this must include depression (grade B). Despite some limitations, a trial helps patient selection and provides patients with an opportunity to

experience the therapy. These recommendations are expected to guide practicing physicians and other stakeholders and should not be mistaken as practice standards. Physicians should continue to make their best judgment based on individual patient considerations and preferences.

American Society of Interventional Pain Physicians
In 2013, the American Society of Interventional Pain Physicians updated its evidence-based guidelines on interventional techniques for the management of chronic spinal pain.[91,] The guidelines included a statement that there is fair evidence for the following recommendation for SCS: "spinal cord stimulation is indicated in chronic low back pain with lower extremity pain secondary to failed back surgery syndrome, after exhausting multiple conservative and interventional modalities". No updates have been made since the original publication.

American Society of Pain and Neuroscience
The American Society of Pain and Neuroscience issued a comprehensive guideline in 2021 on the management of cancer-related pain.[92,] The guideline found that SCS may be considered for 1) treatment of refractory cancer pain (level II-3-C evidence: multiple series compared over time, with or without intervention, and surprising results in noncontrolled experience; treatment is neither recommendable nor inadvisable), and 2) on a case-by-case basis for "pain that is related to cancer treatment such as chemotherapy-induced peripheral neuropathy" (level III-C evidence: clinical experiences-based opinions, descriptive studies, clinical observations, or reports of expert committee; treatment is neither recommendable nor inadvisable).

The American Society of Pain and Neuroscience published consensus guidelines on interventional therapies for knee pain in 2022.[93,] The guidelines state that "Chronic pain that is refractory to acute treatment is managed by progressing to spinal cord stimulator, dorsal root ganglion stimulator, or botulinum toxin (Botox) injection." They also include the statement that "DRG [Dorsal Root Ganglion Stimulation] is a safe and effective treatment option for chronic post-surgical and focal neuropathic pain of the knee (ie, complex regional pain syndrome [CRPS]); Level I, Grade A, Consensus Strong."

The American Society of Pain and Neuroscience published consensus guidelines on interventional therapies for back pain in 2022. [94,] The guidelines recommendations for SCS are summarized in Table 10.

Table 10. American Society of Pain and Neuroscience Recommendations for Spinal Cord Stimulation for Back Pain

Recommendation	Grade	Level of evidence	Level of certainty of net benefit
Following lumbar surgery	A	I-A	Strong
Treatment of non-surgical low back pain	B	I-C	Moderate
Treatment of lumbar spinal stenosis	C	I-C	Moderate

National Institute for Health and Care Excellence
In 2008, NICE issued guidance on spinal cord stimulation for chronic pain of neuropathic or ischemic origin, which was reaffirmed in 2014.[95,] The NICE recommended SCS as a treatment option for adults with chronic pain of neuropathic origin (measuring at least 50 mm on a 0 to 100 mm visual analog scale) that continues for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of an assessment by a specialist team.

In the same guidance, the NICE stated that SCS was not recommended for chronic pain of ischemic origin except in the context of research.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 11.

Table 11. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05466110	sPinal coRd stimulatiOn coMpared With Lumbar InStrumEntation for Low Back Pain After Previous Lumbar Decompression (PROMISE): a Prospective Randomized Controlled Study	84	May 2025
NCT04915157	Efficacy of Spinal Cord Stimulation in Patients With Refractory Angina Pectoris; a Randomized Controlled Trial	72	Jun 2025
NCT05372822	Spinal Cord Burst Stimulation for Chronic Radicular Pain Following Lumbar Spine Surgery: A Randomized Double-blind Sham-controlled Crossover Trial	50	Aug 2025
NCT03681262	Comparing Long-Term Effectiveness of High Frequency and Burst Spinal Cord Stimulation	7	Dec 2026
Unpublished			

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array
• 95970	• Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters,

CPT/HCPCS	
	responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system (eff 1/1/2023)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed
0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact

CPT/HCPCS	
	group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closedloop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters

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03-28-2012	Policy added to the bcbsks.com web site.
04-26-2013	Updated Rationale section.
	Updated Reference section.
	Added ICD-10 Diagnosis Codes *(Effective October 1, 2014)*
03-18-2015	Description section updated
	In Policy section: ▪ In Item A removed "all" and added "reasonable" to read "Spinal cord 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 reasonable pain therapies, when performed according to policy guidelines." ▪ In Item B added "primary", "improve perfusion to", and "non-neuropathic" to read "Spinal cord stimulation is considered experimental / investigational in all other situations including but not limited to primary treatment of critical limb ischemia as a technique to improve perfusion to forestall amputation, treatment for refractory angina pectoris and treatment of non-neuropathic cancer-related pain." In Policy Guidelines: ▪ In Item 1 removed "only as a last resort, other" and "surgical" and added "when reasonable conservative" to read "The treatment is used when reasonable conservative treatment modalities (pharmacological, psychological, or physical, if applicable)…" ▪ In Item 2 removed "i.e., resulting from actual damage to the peripheral nerves" to read "Pain is neuropathic in nature. Common indications include,…" ▪ In Item 4 removed "50%" and "with a temporarily implanted electrode precedes" and added "70%" and "during a typical 5 to 7 day temporary trial electrode array implant prior to" to read "Demonstration of at least 70% pain relief during a typical 5 to 7 day temporary trial electrode array implant prior to permanent implantation" ▪ In Item 6 added "Prior to trial implantation" and "no contraindications to" to read "Psychological evaluation prior to trial implantation has been performed and indicates no contraindications to spinal cord stimulation."
	Rationale section updated
	In Coding section: ▪ Revised CPT code: 95972 *(Effective January 1, 2015)* ▪ Removed ICD-10 Diagnoses: G56.40, G57.70, G90.50, G90.519, G90.529, M50.10, M54.10, M54.30, M54.40, M79.603, M79.606, M79.609, M79.621, M79.629, M79.639, M79.643, M79.646, M79.659, M79.669, M79.673, M79.676
	References updated
01-01-2016	In Coding section: ▪ Revised nomenclature to CPT code 95972. ▪ Removed CPT code 95973.
07-22-2016	Updated Description section.
	In Policy section: ▪ In Item A, added "with standard (non-high-frequency) stimulation" and "all" and removed "reasonable" to read "Spinal cord stimulation with standard (non-high-

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	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 performed according to policy guidelines." ▪ In Item B, added "and", "of", and "heart failure" and removed "primary", "as a technique to improve perfusion", and "for", to read "Spinal cord stimulation is considered experimental / investigational in all other situations, including, but not limited to, treatment of refractory angina pectoris, heart failure, and treatment of non-neuropathic cancer-related pain." ▪ Added Item C, "High-frequency spinal cord stimulation is experimental / investigational for the treatment of severe and chronic pain of the trunk or limbs."
	Updated Rationale section.
	Updated References section.
10-01-2016	In Coding section: ▪ Added ICD-10 codes effective 10-01-2016: G56.43, G57.73, M50.121, M50.122, M50.123 ▪ Termed ICD-10 code effective 09-30-2016: M50.12
06-09-2017	Updated Description section.
	In Policy section: ▪ In Item A, added "or" and removed "(non-" and ")" to read, "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 performed according to policy guidelines." ▪ Removed previous Item C, "High-frequency spinal cord stimulation is experimental / investigational for the treatment of severe and chronic pain of the trunk or limbs." ▪ Added new Item C, "Wireless injectable dorsal root ganglion neurostimulation is experimental / investigational for treatment of severe and chronic pain of the trunk or limbs."
	Updated Rationale section.
	Updated References section.
08-15-2017	Title of policy changed from "Spinal Cord Stimulation."
	Updated Description section.
	In Policy section: ▪ In Item C, added "considered" and removed "Wireless injectable" to read, "Dorsal root ganglion neurostimulation is considered experimental / investigational for treatment of severe and chronic pain of the trunk or limbs." ▪ Updated Policy Guidelines.
	Updated Rationale section.
07-06-2018	Published to the bcbsks.com website on June 6, 2018, with an effective date of July 6, 2018.
	In Policy section: ▪ In Item A, added "and dorsal root ganglion neurostimulation" to read, "Spinal cord stimulation and dorsal root ganglion neurostimulation 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 performed according to policy guidelines." ▪ In Item B, added "and dorsal root ganglion neurostimulation" to read, "Spinal cord stimulation and dorsal root ganglion neurostimulation is considered experimental / investigational in all other situations, including, but not limited to, treatment of critical limb ischemia to forestall amputation and treatment of refractory angina pectoris, heart failure, and treatment of non-neuropathic cancer-related pain.

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	▪ In Item C, added "wireless injectable" and removed "for treatment of severe and chronic pain of the trunk or limbs" to read, "Wireless injectable dorsal root ganglion neurostimulation is considered experimental / investigational."
	Updated Rationale section.
	In Coding section: ▪ Added HCPCS codes: C1767, C1778, C1787, C1820, C1822, C1883, C1897, L8679. ▪ Removed ICD-9 codes.
	Updated References section.
01-01-2019	In Coding section: ▪ Revised nomenclature to CPT codes: 95970, 95971, 95972.
05-21-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
08-28-2019	In Policy section: ▪ In Policy Guidelines Item 1 d, added "during a typical 5 to 7 day temporary trial electrode array implant" and removed "with a temporary implanted electrode" to read, "Demonstration of at least 70% pain relief during a typical 5 to 7 day temporary trial electrode array implant prior to permanent implantation".
	Updated References section.
04-16-2021	Updated Description section
	Updated Rationale section
	Updated references
06-01-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed Coding bullets o In 2016, a HCPCS "C" code was issued for high-frequency neurostimulator generator: C1822. o The Centers for Medicare & Medicaid Services has issued instructions that the existing implantable neurostimulator code C1820 should only be used for stimulators that are not high frequency. ▪ Converted ICD-10 Codes to code ranges
	Updated References Section
06-22-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Added C1826 ▪ Removed ICD-10 codes
	Updated References Section
01-01-2024	Updated Coding Section ▪ Updated nomenclature for 63685 and 63688 ▪ Added 0784T, 0785T, 0786T, 0787T, 0788T, 0789T
05-28-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
06-10-2025	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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