MEDICAL POLICY

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Medical Policy Title	**Spinal Cord Stimulation / Dorsal Column Stimulation**
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Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Failed Back Surgery Syndrome (FBSS)

I. A non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator (SCS) is considered **medically appropriate** as follows:

   A. For a short-term trial (i.e., greater than 48 hours) of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator **ALL** of the following criteria must be met:

      1. Performed for the treatment of chronic intractable pain secondary to failed back surgery syndrome (FBSS) with intractable neuropathic leg pain (after prior surgery in the same spinal region);
      2. Failure of at least six (6) consecutive months of physician-supervised, conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
      3. Surgical intervention is not indicated, or the patient does not wish to proceed with spinal surgery;
      4. Attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of inadequately controlled mental or behavioral health conditions/issues (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain, and/or negatively impact the success of an SCS or contraindicate its placement. (See Policy Guidelines).

   B. For permanent implantation of a non-high-frequency or high-frequency (HF 10 SCS]) dorsal column spinal cord stimulator, **BOTH** of the following must be met:

      1. All criteria for the short-term trial SCS are met;
      2. There is documented pain relief of at least 50% during a short-term trial of spinal cord stimulation.

Painful Diabetic Peripheral Neuropathy (PDPN)

II. A non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator is considered **medically appropriate** as follows:

A. For a short-term trial (i.e., at least five [5] days) of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator, **ALL** of the following must be met:
    1. Performed for the treatment of chronic, intractable pain secondary to diabetic peripheral neuropathy in the lower extremities;
    2. Symptoms include **both** of the following:
        a. Lower extremity neuropathic pain for >12 months; **and**
        b. Pain is rated at least Visual Analogue Scale (VAS) ≥5;
    3. Ineffective pain relief with or intolerance to **at least two (2)** of the following:
        a. Anticonvulsants;
        b. Tricyclic antidepressant;
        c. Serotonin-norepinephrine reuptake inhibitor (SNRI); **or**
        d. Opioids; if taking opioids, the daily use is ≤100MME (morphine milligram equivalent) per day.
    4. Hemoglobin A1c (HbA1c) <10% within three (3) months prior to the trial;
    5. There are no other medical diagnoses (e.g., chronic inflammatory demyelinating polyneuropathy [CIDP]; Hepatitis B; HIV; Lyme disease; chemotherapy or vitamin deficiency induced neuropathy) that are concordant with the presenting symptoms, signs, and results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.);
    6. Attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment [with or without psychological questionnaires and/or psychological testing]) reveals no evidence of inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) that would impact perception of pain, and/or negatively impact the success of a SCS or contraindicate placement of the device (see Policy Guidelines).

B. For permanent implantation of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator, **BOTH** of the following criteria must be met:
    1. All criteria for the short-term trial SCS are met;
    2. There is documented pain relief of least 50% during a short-term trial of SCS.

<u>Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)</u>

III. A non-high-frequency dorsal column spinal cord stimulator is considered **medically appropriate**, as follows:

A. For a short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator, **ALL** of the following criteria must be met:
    1. Performed for the treatment of chronic, intractable pain secondary to CRPS/RSD of the

upper and lower extremities;

2. The diagnosis is limited to only the extremities and not to the head/face/neck, trunk, perineum/pelvis, or abdominal viscera;
3. Diagnostic criteria for CRPS/RSD meets **all** of the following:
    a. Presence of continuing pain which is disproportionate to any inciting event;
    b. Patient reports **at least one (1)** symptom in at least **three (3)** of the following categories:
        i. Sensory: reports of hyperesthesia (increased sensitivity to sensory stimuli) and/or allodynia (pain to light touch);
        ii. Vasomotor: reports of temperature asymmetry, skin color changes, or skin color asymmetry;
        iii. Sudomotor/edema: reports of edema, sweating changes, or sweating asymmetry; **or**
        iv. Motor/trophic: reports of decreased range of motion, motor dysfunction (weakness, tremor, dystonia), trophic changes (hair, nail, skin);
    c. On physical exam, the patient must display **at least one (1)** sign in at least **two (2)** of the following categories:
        i. Sensory: evidence of hyperalgesia (pain to pinprick) or allodynia (pain to light touch),
        ii. Vasomotor: evidence of temperature asymmetry, skin color changes, or asymmetry,
        iii. Sudomotor/edema: evidence of edema, sweating changes, or sweating asymmetry, **or**
        iv. Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia) or trophic changes (hair, nail, skin); **and**
    d. There are no other medical or psychological diagnoses that are concordant with the presenting symptoms, signs, or results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.);
4. Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification);
5. Surgical intervention is not indicated;
6. Attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment [with or without psychological questionnaires or psychological testing]) reveals no evidence of inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain or

negatively impact the success of a SCS or contraindicate its placement.

B. For permanent implantation of a non-high-frequency dorsal column spinal cord stimulator, **BOTH** of the following must be met:

1. All criteria for a short-term trial spinal cord stimulator are met;
2. There is documented pain relief of at least 50% during a short-term trial of spinal cord stimulation.

Chronic Critical Limb Ischemia (CLI)

IV. A non-high-frequency dorsal column SCS is considered medically **appropriate** as follows:

A. For a short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator, **ALL** of the following criteria must be met:

1. Performed for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI);
2. Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction;
3. Diagnostic criteria for critical limb ischemia have met **all** of the following:
   a. Ischemic limb rest pain;
   b. Rutherford Classification Grade II, Category 4 (see Description section), ischemic rest pain that is characterized by **both** of the following:
      i. Resting ankle pressure less than 40 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; **and**
      ii. Toe pressure less than 30 mmHg;
4. Advanced imaging (i.e., angiographic, computed tomography [CT] or magnetic resonance imaging [MRI]) demonstrates multi-level disease with absence of named vessel with flow into the foot;
5. Attestation by a behavioral health provider (i.e., a face-to-face or virtual aassessment, with or without psychological questionnaires) reveals no evidence of inadequately controlled behavioral health conditions/issues (e.g., substance use disorder(s), depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

B. For permanent implantation of a non-high-frequency dorsal column spinal cord stimulator, **BOTH** of the following must be met:

1. All criteria for a short-term trial spinal cord stimulator are met;
2. There is documented pain relief of at least 50% during a short-term trial of SCS.

Chronic Stable Angina Pectoris/Myocardial Ischemia

V. A non-high-frequency dorsal column spinal cord stimulator is considered **medically appropriate** as follows:

   A. For a short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column SCS, **ALL** of the following criteria must be met:

      1. Performed for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia;
      2. Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see Description section);
      3. Attestation by the individual's treating cardiologist confirms that the individual meets **both** of the following:
         a. Coronary artery disease (CAD) diagnosis; **and**
         b. Is not a suitable candidate for a revascularization procedure;
      4. Failure to adequately improve anginal symptoms with optimal medical treatment (OMT), including **all** the following:
         a. anti-platelet therapy;
         b. statin and/or other lipid-lowering therapy;
         c. anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute; **and**
         d. anti-hypertensive therapy (as indicated) to pursue a goal systolic blood pressure (SBP) of less than or equal to 140 mmHg and a goal diastolic blood pressure (DBP) less than or equal to 90 mmHg;
      5. Attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of inadequately controlled behavioral health condition/issue (e.g., substance use disorder(s), depression, or psychosis) that would impact perception of pain or negatively impact the success of an SCS or contraindicate its placement.

   B. For permanent implantation of a non-high-frequency dorsal column spinal cord stimulator, **BOTH** of the following must be met:

      1. All criteria for a short-term trial spinal cord stimulator are met;
      2. There has been a beneficial clinical response during a short-term trial of SCS.

Replacement of Dorsal Column Spinal Cord Stimulator

VI. Replacement of an existing high-frequency or non-high-frequency dorsal column spinal cord stimulator, or replacement of an existing dorsal root ganglion (DRG) stimulator with another DRG is considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The existing stimulator or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty;

B. Revision of the electrode percutaneous array(s) or electrode plate/paddle(s) is required.

VII. Replacement of a functioning non-high-frequency dorsal column spinal cord stimulator with a high-frequency dorsal column spinal cord stimulator is considered **not medically necessary**.

Non-Indications for Dorsal Column Spinal Cord Stimulator

VIII. If the initial short-term trial dorsal column spinal cord stimulator fails, a repeat trial is considered **not medically necessary** for any indication.

IX. A non-high-frequency or high-frequency dorsal column spinal cord stimulator is considered **investigational** for **ANY** other indication or condition, including but not limited to:

A. Peripheral neuropathy, other than painful diabetic peripheral neuropathy); Abdominal/pelvic visceral pain;

B. Abdominal pain related to celiac artery compression syndrome;

C. Chronic cervical or lumbar radiculopathy without prior surgery;

D. Chronic cervical, thoracic, or lumbar axial pain without prior spinal surgery;

E. Dysesthesias involving the lower extremities secondary to spinal cord injury;

F. Failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arms(s) or trunk;

G. Neuropathic pain associated with Multiple Sclerosis;

H. Post-amputation pain (phantom limb pain);

I. Post-herpetic neuralgia.

X. A high-frequency dorsal column spinal cord stimulator is considered **investigational** for **ALL** other indications, including CRPS/RSD.

XI. Generator modes other than tonic-low and high-frequency (e.g., burst stimulation) are considered **investigational**.

Dorsal Root Ganglion (DRG) Stimulator

XII. Placement of a DRG stimulator is considered **investigational** for **ALL** indications.

XIII. Replacement of a dorsal column spinal cord stimulator with a DRG stimulator is considered **investigational** for **ALL** indications, except as noted in Policy Statement VI.

Peripheral Nerve Stimulation

XIV. Peripheral nerve stimulation, including peripheral nerve field stimulation is considered **investigational** for treatment of acute or chronic pain conditions, including **ANY** of the following:

A. Chronic critical limb ischemia (CLI);

B. Chronic stable angina pectoris;

C. Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD);

D. Dysesthesias involving the lower extremities secondary to spinal cord injury;

E. Failed back surgery syndrome (FBSS) with intractable neuropathic leg pain;

F. Post-amputation pain (phantom limb pain);

G. Post-herpetic neuralgia;

H. Peripheral neuropathy.

RELATED POLICIES

Corporate Medical Policy

1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

3.01.24 Neuropsychological and Psychological Testing

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. This medical policy criteria are not applicable to the following: simple or complex brain neurostimulator pulse generators/transmitters, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter.

II. A dorsal column SCS capable of using either high-frequency or non-high-frequency stimulation (dual-mode) is considered an equally effective alternative (when the device uses non-high-frequency stimulation) for the treatment of any of the medically necessary indications listed above.

III. A dorsal column spinal cord stimulator using high-frequency is considered an equally effective alternative to non-high-frequency dorsal column spinal cord stimulator only for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBS).

IV. The implantation of an SCS is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) need to have been tried and failed or have been judged unsuitable or contraindicated.

V. Patients must be carefully screened, evaluated, and diagnosed by a multidisciplinary team, prior to application of these therapies. This evaluation may include a psychological evaluation/assessment to exclude any psychiatric or psychosocial history that would negatively influence the outcome of the treatment. Psychological testing is not specifically required; however, if necessary, refer to the policies in the Related Policies section above.

DESCRIPTION

Spinal cord stimulation is a neuromodulation technique for the treatment of chronic pain involving

implantation of electrodes in the epidural space to deliver electrical impulses to the dorsal columns of the spinal cord, inhibiting pain signal transmission. The procedure involves a short-term trial period of temporary spinal cord stimulation to determine whether sufficient pain relief is achieved to render permanent implantation medically necessary. Related neuromodulation techniques include dorsal root ganglion stimulation, which targets the dorsal root ganglia rather than the spinal cord.

Definitions

Complex regional pain syndrome (CRPS) (as defined by the International Association for the Study of Pain [IASP]) is variety of painful conditions following injury which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event and often resulting in significant impairment of motor function, and showing variable progression over time. In addition to injury, CRPS can a so occur as a result of various medical disorders or illnesses.

Critical limb ischemia (CLI) is a clinical syndrome of ischemic pain at rest and ischemic tissue loss such as non-healing ulcers or gangrene, related to peripheral artery disease (PAD) of the lower limbs. Spinal stimulators may be appropriate for the treatment of intractable rest pain secondary to chronic limb ischemia.

- Ischemic Rest Pain is pain that occurs in the toes or in the area of the metatarsal heads. Occasionally, it occurs in the foot proximal to the metatarsal heads. Elevation of the limb above or at the horizontal position aggravates the pain and pendency, to some degree at least, brings relief. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.
- Refer to Rutherford classification table below.

Dorsal root ganglion (DRG) Stimulation is an emerging method of treatment for neuropathic pain. With DRG stimulation, leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. The procedure initially involves a short-term trial (i.e., greater than 48 hours) using an external pulse generator; upon success of the initial a permanent pulse generator may then be implanted.

- At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions rem ins under investigation.

Failed back surgery syndrome (FBSS) is lumbar spinal pain of unknown origin despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same spinal region. Procedures/surgery that do not encroach into the spinal canal (e.g., basivertebral nerve ablation [BVNA], interspinous/interlaminar/facet distraction, kyphoplasty/vertebroplasty surgery) are not considered surgical interventions associated with FBSS.

High-frequency spinal cord stimulation (HF-SCS), (also referred to as kilohertz frequency spinal cord stimulation or HF10) is a type of spinal cord stimulation (SCS) providing a higher frequency than traditional spinal cord stimulator systems. The HF10 SCS uses low-amplitude, high-frequency, and short-duration pulses. HF10 SCS does not generate paresthesia and operates at a frequency of

10,000 Hz to provide pain relief in comparison to traditional spinal cord stimulation systems, which operate at a frequency in the range of 40-60 Hz and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation, HF10 SCS is proven safe and effective for treatment of chronic, intractable low back and leg pain in patients with failed back surgery syndrome (FBSS).

Ischemic rest pain is pain that occurs in the toes or in the area of the metatarsal heads. Occasionally, it occurs in the foot proximal to the metatarsal heads. Elevation of the limb above or at the horizontal position aggravates the pain and positioning the limb in a dependent position pendency, tends to improve the pain to some degree at least, brings relief. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.

Painful diabetic peripheral neuropathy (PDPN) is a progressive neurological disorder accompanied by neuropathic pain caused by diabetes mellitus.

Peripheral nerve field stimulation is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a region of affected nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

Peripheral nerve stimulation involves implantation of electrodes near or on a peripheral nerve to reduce pain. The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

Spinal cord stimulation (SCS), (also known as dorsal column stimulation or neuromodulation) is a reversible therapy applied for neuropathic pain with techniques that include multi-output implanted pulse generator and a choice of electrodes, some of which can be placed percutaneously. The technical goal of this therapy is to achieve stimulation of paresthesia of the dorsal horn of the spinal cord at a subjectively comfortable level, overlapping an individual's topography of pain. The procedure initially involves a short-term trial (e.g., greater than 48 hours) of percutaneous (temporary) spinal cord stimulation, prior to the subcutaneous (permanent) implantation of the spinal cord stimulator device, to determine whether the spinal cord stimulator will induce sufficient pain relief to render it medically necessary.

Rutherford Classification (Rutherford 1997). Refer to the policy statement for treatment of patients with chronic, intractable pain secondary to chronic critical limb ischemia (CLI):

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic- no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg, but at least 20

			mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise and AP after exercise < 50 mmHg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mmHg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
	6	Major tissue loss- extending above TM level, functional foot no longer salvageable	Same as category 5
AP: ankle pressure; PVR: pulse volume recording; TM: trans metatarsal; TP: toe pressure			

Class	**New York Heart Association Functional Classification**	**Canadian Cardiovascular Society (CCS) Functional Classifications.**
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair-climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2006; Gibbons, 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

SUPPORTIVE LITERATURE

Dorsal Column Spinal Cord Stimulation (SCS)

Randomized controlled trials (RCT) and systematic reviews support the use of dorsal column spinal cord stimulation stimulator (SCS) for chronic neuropathic pain in appropriately selected patients who have failed conservative management. A temporary trial is required to determine effectiveness (≥50% pain relief) prior to permanent implantation. Literature supports the value of presurgical psychological evaluation to identify factors that may adversely impact functional outcomes after spinal cord stimulation (Doleys 2006; Celestin 2009; North American Spine Society [NASS] 2017).

Failed Back Surgery Syndrome (FBSS)

For FBBS with predominant leg pain, the PROCESS RCT demonstrated that SCS provides superior pain relief, functional capacity, and quality of life compared with conventional medical management alone, with benefits sustained through 24-month follow-up (Kumar 2007, 2008). Systematic reviews confirm these findings (Frey 2009; Taylor 2005, 2014; Kapural 2017; Grider 2016). A Cochrane review (O'Connell 2021) found moderate-certainty evidence supporting SCS for chronic pain, while noting the need for longer-term sham-controlled data. A JAMA Network Open systematic review and network meta-analysis (Huygen 2024) confirmed SCS superiority over medical management for chronic back and leg pain.

High-Frequency Stimulation for FBSS and Chronic Back/Leg Pain

As an alternative to traditional dorsal spinal column stimulation, HF 10 spinal cord stimulation is proven safe and effective for the treatment of chronic, intractable low-back and leg pain in patients with FBSS. The SENZA-RCT demonstrated superiority of 10-kHz SCS over traditional low-frequency SCS for chronic back and leg pain at 12 and 24 months (Kapural 2015, 2016). Additional RCTS and

systematic reviews support HF10 efficacy (Perruchoud 2013; Bicket 2016; De Andres 2017; Bolash 2019; Petersen 2021; Kapural 2022). A Cochrane review of SCS for low back pain (Traeger 2023) found low-certainty evidence that high-frequency SCS may reduce pain and disability compared with conventional medical management.

Complex Regional Pain Syndrome (CRPS)

Randomized trials and meta-analyses support SCS for CRPS, demonstrating reduction in pain intensity and improved quality of life compared with conservative therapy (Kemler 2006, 2008; Ho 2022). A Cochrane overview of CRPS interventions (Ferraro 2023) found low-certainty evidence supporting SCS. A Lancet Neurology review (Ferraro 2024) confirmed SCS as an established neuromodulation option for refractory CRPS. The evidence base for CRPS consists primarily of studies using traditional low-frequency stimulation.

Painful Diabetic Neuropathy (PDN)

Earlier RCTs using low-frequency SCS also demonstrated efficacy for PDN (de Vos 2014; Slangen 2014; van Beek 2015, 2018). Zuidema et al (2022) published long-term follow-up (8–10 years) which showed sustained pain reduction in patients who continued SCS therapy.

Petersen et al (2021, 2022, 2023, 2025) conducted the SENZA-PDN study, a prospective, multicenter, open-label RCT (n=216) comparing 10-kHz SCS plus conventional medical management (CMM) with CMM alone in patients with PDN refractory to gabapentinoids and at least one other analgesic class. At 6 months, 79% of SCS patients achieved ≥50% pain relief versus 5% with CMM alone (P<.001), with mean pain VAS decreasing from 7.6 to 1.7 cm. Neurological improvements were observed in 62% of SCS patients versus 3% of conventional medical management (CMM) patients (P<.001). At 12 months, 85% maintained ≥50% pain relief with average 74.3% pain reduction (Petersen 2022). At 24 months, 90.1% achieved ≥50% pain relief with mean 79.9% pain reduction, and 65.7% demonstrated clinically meaningful neurological improvement (Petersen 2023). A longer-term post-study survey at median 4.1 years showed sustained pain relief in 76.8% and quality-of-life improvement in 84.6% of respondents (Petersen 2025).

Duarte et al (2022) conducted a systematic review and network meta-analysis of 3 RCTs comparing different SCS waveforms for PDN, with searches through December 2021. Significant reductions in pain intensity were observed for both low- and high-frequency SCS (95% CI, moderate certainty) compared with CMM alone. HF-SCS showed a significantly greater reduction in pain intensity compared with LF-SCS (95% CI, moderate certainty). Both LF-SCS and HF-SCS were superior to CMM for the proportion of patients achieving ≥50% pain reduction and health-related quality of life (very low to moderate certainty), though no significant differences were observed between LF-SCS and HF-SCS for these secondary outcomes (very low to moderate certainty). Limitations included the limited number of RCTs available and the absence of head-to-head RCTs comparing SCS waveforms, which means the relative benefits of HF-SCS compared with LF-SCS for patients with PDN remain uncertain.

Chen et al (2022) conducted a retrospective, multicenter, real-world analysis of high-frequency 10 kHz SCS for the treatment of painful diabetic peripheral neuropathy (pDPN). The study assessed pain relief and functional improvements for 89 consecutive patients aged ≥18 years with diabetic neuropathy who were permanently implanted with a 10 kHz SCS device. Available data were

extracted from a commercial database. At the last assessment, 79.5% (58/73) of patients with available follow-up data were treatment responders, defined as having at least 50% patient-reported pain relief from baseline, at a mean follow-up of 21.8 months (range: 4.3 to 46.3 months). Patients also reported improvements in sleep and overall function. Limitations included the retrospective design, lack of a control group, reliance on patient-reported pain relief without standardized pain scales, data extraction from a commercial database, and loss of 16 patients to follow-up (73 of 89 with outcome data available).

Chen et al (2022) conducted a retrospective, multicenter, real-world analysis of high-frequency 10 kHz SCS for the treatment of painful diabetic peripheral neuropathy (pDPN). The study included 89 consecutive patients aged ≥18 years with diabetic neuropathy who were permanently implanted with a 10 kHz SCS device between May 2017 and November 2020. Patients who reported at least 50% pain relief during the trial period were eligible to receive permanent device implantation. The real-world data showed 79.5% responder rates at mean 21.8-month follow-up.

Abbas et al (2025) conducted a systematic review and meta-analysis evaluating SCS compared with best medical therapy (BMT) for PDN, including nine clinical trials (407 patients) with follow-up ranging from 6 to 24 months. SCS demonstrated significant pain reduction compared with BMT ($P<0.00001$), with benefits observed for both conventional SCS ($P<0.001$) and 10-kHz SCS ($P<0.001$). SCS achieved higher treatment success rates (≥50% pain relief) than BMT ($P<0.00001$) and significantly improved the EuroQol-5 Dimension utility index ($P<0.00001$) and self-reported health ($P=0.005$). The authors concluded that this meta-analysis provides robust evidence supporting SCS as an effective intervention for managing chronic pain and enhancing quality of life in patients with PDN.

Awad et al (2026) conducted a meta-analysis of randomized controlled trials evaluating SCS for PDN, including seven RCTs in the qualitative synthesis and three in the quantitative meta-analysis. Compared with conventional medical management alone, SCS was associated with significant improvements in pain intensity ($P<0.001$) and quality of life ($P<0.001$), with a significantly higher proportion of patients achieving ≥50% pain relief ($P<0.001$). No significant differences were observed in complication rates between groups. The authors concluded that SCS provides clinically meaningful improvements in pain and quality of life without an increase in adverse events.

Postherpetic Neuralgia (PHN)

Abbas et al (2025) conducted a systematic review and meta-analysis comparing temporary SCS (without implantable pulse generator) with pulsed radiofrequency (PRF) in PHN management, including 4 RCTs (125 SCS patients, 136 PRF patients) through January 1, 2025. SCS significantly reduced pain intensity after one month (MD: -0.98, 95% CI), three months (MD: -1.34, 95% CI), and six months (MD: -1.27, 95% CI). Treatment success (>50% pain reduction) favored SCS at three months and beyond (risk difference: 0.37, 95% CI). SCS significantly reduced pregabalin use at three months (MD: -27.88 mg, 95% CI) and 12 months. Quality-of-life improvements were significant for SF-36 bodily pain and physical role domains from six months onward. The authors concluded that SCS outperformed PRF in mid- and long-term outcomes for PHN, including pain reduction, treatment success, and quality-of-life improvements, while noting that PRF remains a viable short-term alternative. The authors recommended that further research focus on the cost-effectiveness, safety,

and long-term efficacy of this approach. Limitations included the small number of included RCTs (4 studies), the relatively small total sample size (261 patients), and that all included RCTs were conducted in China, which may limit generalizability.

Chronic Critical Limb Ischemia (CLI)

There is evidence to favor SCS over standard conservative treatment to improve limb salvage, pain relief, and clinical status in patients with non-reconstructable chronic critical limb ischemia (Ubbink 2013; Asimakidou 2022). Evidence is based on traditional low-frequency stimulation parameters.

Chronic Refractory Angina Pectoris

Meta-analyses demonstrate that SCS is associated with increased exercise duration, reduced angina frequency, and decreased nitrate consumption in patients with refractory angina who are not candidates for revascularlion (Taylor 2009; Pan 2017). Evidence is based on traditional low-frequency stimulation parameters.

Spinal Cord Stimulation for Multiple Sclerosis (MS) Symptoms

Rapisarda et al (2021) conducted a systematic review of SCS in MS patients (7 studies). A total of 373 patients with MS submitted to a stimulation trial and 82 patients underwent a de novo implantation. The efficacy of SCS was higher for urinary dysfunction (p =0.0144) and neuropathic pain (p= 0.0030) compared with motor disorders. Improvement was reported in 55.8% of patients with motor disorders, 67.1% with urinary dysfunction, and 82.4% with neuropathic pain, though the authors noted further studies are needed to improve patient selection and clarify optimal timing.

Goodwin et al (2023) conducted a narrative systematic review from 16 articles to determine the efficacy of SCS in the treatment of MS spasticity, concluding that "although a unique modality, there is not enough evidence to support the employment of SCS over current medical standard of care."

Jung et al (2024) conducted a systematic review of epidural SCS for spasticity (n=34 studies, including patients with MS). Pooled subjective improvement in spasticity was 78% with 73% improved ambulation, though up to 10% experienced complications. Patients with spinal causes had better outcomes compared with patients with cerebral causes. Up to 10% of patients experienced complications including infections and hardware malfunction. The authors concluded that while SCS may be a useful tool for spasticity management, significant study heterogeneity and low quality of evidence limit conclusions.

Dorsal Root Ganglion (DRG) Stimulation

Deer et al (2017) conducted the ACCURATE study, a prospective, multicenter, randomized comparative effectiveness trial (n=152) comparing DRG stimulation with conventional or lower-extremity CRPS types I and II. At 3 months, treatment success was 81.2% for DRG versus 55.7% for SCS (P0.001). At 12 months, 74.2% of DRG patients achieved ≥50% pain relief versus 53.0% with SCS (P0.0004), with superior paresthesia targeting (94.5% vs 61.2%). Device-related and serious adverse events were not significantly different between groups. (Eldabe 2022) reported long-term follow-up, showing sustained pain relief at 5–7 years in patients who continued DRG therapy. Pain scores were significantly reduced at 24 months (p=0.03) and at final follow-up (p=0.03). The authors concluded that DRG stimulation can provide effective pain relief and improved quality of life in

patients with neuropathic pain, though the high revision rate and battery life issues were noted.

Moman et al (2021) conducted a systematic review and pooled analysis of DRG stimulation infection rates across procedural stages. Ten studies met inclusion criteria: eight studies reported trial data (n=291 patients), ten studies reported implant data (n=250 patients), and seven studies reported revision data (n=26 patients). The pooled infection incidence was 1.03% for trials, 4.80% for permanent implants, and 2.82% overall, with a statistically significant difference between stages (P=0.01), supporting the requirement for a trial period prior to permanent implantation. The authors concluded that DRG stimulation trials appear to be low risk for infection, but that risk is significantly increased with permanent implantation.

D'Souza et al (2022) evaluted the current evidence for DRG stimulation in lower extremity neuropathic pain using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) criteria. CRPS types I and II included one RCT and 11 observational studies (3 to 36 months) provided low-quality evidence of improved pain intensity. Evidence for DRG stimulation in painful diabetic neuropathy, focal neuropathy, polyneuropathy, and postsurgical neuropathic pain was rated very low quality. The authors concluded that future adequately powered RCTs are warranted.

Rigoard et al (2025) conducted the BOOST-DRG study, a prospective, multicenter, randomized, double-blind, crossover trial comparing SCS, DRG stimulation (DRGS), and combined SCS+DRGS (DUAL) in patients with persistent spinal pain syndrome after spinal surgery (PSPS-T2). The study aimed to compare the pain relief (≥50%) responder rates through a three-month randomized crossover trial. After the crossover period, stimulation programming was switched to Burst. Secondary objectives included evaluating clinical efficacy at three-, four-, six-, and 12-month follow-ups, assessing pain intensity, area of pain, area of paresthesia coverage, quality of life, functional disability, psychological distress, medication intake, and the Multidimensional Clinical Response Index (MCRI). Responder rates (≥50% pain relief) were similar across all three modalities (60%; P=0.84) but increased to 80% when patients could switch between stimulation options. Clinical outcomes significantly improved through 12-month follow-up compared with baseline. The authors concluded that the ability to stimulate different neural structures, separately or simultaneously, led to improved responder rates and allowed patients to personalize treatment.

Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS)

PNFS is being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and postherpetic neuralgia. Evidence for PNS and PNFS for pain remains limited. For PNFS, earlier studies were insufficient to demonstrate net health outcome improvement (Verrills 2011, 2014; McRoberts 2013; Kloimstein 2014; Eldabe 2019).

Van Heteren et al (2023) conducted a multicenter comparative study of SCS+PNFS versus SCS alone in 75 patients with persistent spinal pain syndrome (21 SCS-only, 54 SCS+PNFS). Both groups showed significant reduction in back and leg pain at 12 months, but no significant differences were found between groups in pain, quality of life, disability, or psychological outcomes. The authors concluded that SCS alone provided similar pain relief and quality-of-life improvement as SCS+PNFS, though adding PNFS may be considered in patients with refractory low back pain not responding to

SCS alone.

Burst Stimulation

Hou et al (2016) conducted a systematic review of burst SCS for chronic back and limb pain, identifying five studies (three randomized crossover trials and two case series) with sample sizes ranging from 12 to 48 patients. Data was collected after 1 to 2 weeks of treatment and findings were not pooled. The overall confidence in the evidence for burst SCS was rated as "very low."

Deer et al (2018) conducted the SUNBURST study, an unblinded crossover trial (n=100) to determine the safety and efficacy of a device delivering both traditional tonic stimulation and burst stimulation to patients with chronic pain of the trunk and/or limbs. Following a successful tonic trial, subjects were randomized to receive one stimulation mode for the first 12 weeks, then the other stimulation mode for the next 12 weeks. The study demonstrated noninferiority to tonic stimulation ($P<0.001$), and superiority of burst was also achieved ($P<0.017$). Trial limitations included the crossover design, lack of blinding, and variable burst programming parameters.

Hara et al (2022) conducted a sham-controlled, crossover RCT (n=50) of burst SCS for chronic radicular pain after lumbar surgery. Patients underwent two 3-month periods with spinal cord burst stimulation and two 3-month periods with placebo stimulation in a randomized order. Among 50 patients randomized, 47 (94%) had at least one follow-up Oswestry Disability Index (ODI) score and 42 (84%) completed all stimulation randomization periods. The mean between-group difference in ODI was −1.3 points ($P=0.32$), with no significant difference on any prespecified outcome. This sham-controlled evidence raises uncertainty about the independent efficacy of burst stimulation beyond placebo effects. None of the prespecified secondary outcomes showed a significant difference. Nine patients (18%) experienced adverse events, including 4 (8%) who required surgical revision of the implanted system. The authors concluded that spinal cord burst stimulation, compared with placebo stimulation, resulted in no significant difference in the change from baseline in self-reported back pain–related disability.

Closed-Loop Spinal Cord Stimulation

A novel spinal cord stimulation system, the Evoke Spinal Cord Stimulation (SCS) System, provides the first in vivo, real-time, continuous objective measure of spinal cord activation in response to therapy via recorded evoked compound action potentials (ECAPs) in patients during daily use.

Brooker et al (2021) reported 24-month results from the Avalon study, a prospective, multicenter, single-arm study of 50 patients implanted with the Evoke closed-loop SCS system. The 24-month results support the 12-month results of both the Avalon study and the Evoke study; however, the single-arm design limits the strength of evidence.

Mekhail et al (2020, 2022, 2024) conducted the Evoke study, a multicenter, double-blinded, RCT comparing evoked compound action potential (ECAP)-controlled closed-loop SCS with fixed-output open-loop SCS for chronic refractory back and leg pain refractory. At 12 months, closed-loop SCS showed superiority: 79.1% versus 53.7% achieved ≥50% pain relief without increased medications. At 24 months, a greater proportion of closed-loop patients were holistic responders (49.3% vs 26.9%). At 36 months, 77.6% of closed-loop versus 49.3% of open-loop participants maintained

≥50% pain relief (P<001).

PROFESSIONAL GUIDELINE(S)

American Association of Clinical Endocrinology (AACE)

In 2022, the AACE recommended that neuromodulatory techniques such as high-frequency SCS should be considered for refractory painful diabetic peripheral neuropathy (Grade B). Combining pharmacological approaches (pregabalin, duloxetine, capsaicin 8% patch, gabapentin, and some tricyclic antidepressants) with nonpharmacological approaches should be considered in those with refractory painful diabetic peripheral neuropathy (Grade A and B) (Blonde 2022).

American Society of Pain and Neuroscience (ASPN)

In 2022, ASPN recommended spinal cord stimulation following lumbar surgery (Grade A), for treatment of non-surgical low back pain (Grade B), and for patients with predominate lumbar spinal stenosis (Grade C) (Sayed 2022).

In 2023, ASPN published best practices guidelines for DRG stimulation for chronic pain (Chapman 2023), assigning Grade A evidence for CRPS I and II; Grade B for post-hernia repair pain; Grade C for FBSS, post-joint surgery, peripheral neuropathy, and pelvic pain; and Grade I for post-amputation pain and post-herpetic neuralgia (Chapman 2023).

In 2024, ASPN published the SWEET guidelines for PDN (Sayed 2024), recommending:

- Clinicians should offer agents from serotonin-norepinephrine reuptake inhibitor (SNRI), gabapentinoids, and tricyclic anti-depressant (TCA) classes of medication (Grade A);
- Opioids are often accompanied by side effects and therefore their use is not recommended (Grade B);
- SCS for patients with lower extremity PDN after the failure of other non-invasive FDA approved treatments;
- Consideration of PNS for patients with focal lower extremity PDN who have failed conservative therapies and are not candidates for SCS (Grade C).

American Society of Regional Anesthesia and Pain Medicine (ASRAPM)

In 2023, ASRAPM (Shanthanna 2023) issued consensus guidelines recommending:

- SCS trial is recommended for the following patient populations (all Grade B):
  - Chronic low back pain and/or leg pain
  - Critical limb ischemia due to peripheral vascular disease
  - Chronic painful diabetic neuropathy
  - Complex regional pain syndrome (CRPS) type I or II
  - Chronic anginal pain in non-surgical candidates (trial may not be needed in this group)

- A trial of SCS before permanent implant (with the exception of chronic anginal pain in non-surgical candidates), requiring ≥50% pain relief on a validated instrument (Grade B).
- Screening all patients for psychosocial factors including depression (Grade B).
- Trial duration exceeding 10 days is not ordinarily recommended due to increased infection risk.

National Institute for Health and Care Excellence (NICE)

In 2013, without more recent update, NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain, which stated "Current evidence on the efficacy of peripheral nerve-field stimulation for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device."

North American Spine Society (NASS)

The 2017 North American Spine Society's coverage recommendations outline contraindications including repeating a failed SCS trial in the same region, untreated drug addiction, poorly controlled psychiatric disorders, and pregnancy. Demand-type cardiac pacemakers are a relative contraindication.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates spinal cord stimulators (SCS) as medical devices. All SCS including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 May 4]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts FDA [accessed 2026 May 4]

Neurostimulator devices are approved through the premarket approval process under FDA product codes: LGW (spinal cord stimulator, totally implanted, for pain relief), PMP (dorsal root ganglion stimulator for pain relief), and GZB (spinal cord stimulator, implanted, for pain relief).

Traditional SCS: Totally implantable dorsal column SCS systems are Class III PMA devices. Multiple devices have received FDA PMA approval, including the Precision Spinal Cord Stimulator System and the Genesis IPG System. Systems with external transmitters are Class II 510(k) devices.

High-Frequency SCS: Nevro received FDA approval in May 2015 for the Senza SCS system for chronic pain of the trunk and/or limbs related to FBSS. In July 2021, the FDA expanded the PMA indication for the Senza system at 10 kHz to include chronic intractable pain of the lower limbs associated with diabetic neuropathy.

Burst Stimulation: In October 2016, the FDA approved BurstDR stimulation (St. Jude Medical/Abbott). In February 2023, the FDA expanded the indication for Abbott's Prodigy, Proclaim, and Proclaim XR SCS systems to include treatment of diabetic peripheral neuropathy of the lower extremities using

tonic stimulation mode.

DRG Stimulation: Abbott Medical has FDA approval for the Axium and Proclaim DRG neurostimulator systems for moderate to severe chronic intractable pain of the lower limbs in adults with CRPS types I and II.

Closed-Loop SCS: The Evoke SCS System received FDA approval on February 28, 2022, for chronic intractable pain of the trunk and/or limbs including FBSS, intractable low back pain, and leg pain.

PNFS: There are no FDA-approved devices specifically for peripheral nerve field stimulation.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
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
63650	Percutaneous implantation of neurostimulator electrode array; epidural
63655	Laminectomy for implantation neurostimulator electrode, 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

HCPCS Codes

Code	Description
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
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
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Electrical Nerve Stimulators (NCD 160.7) [accessed 2026 Apr 7]

Peripheral nerve field stimulation (PNFS) is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

11/15/01, 09/19/02, 09/18/03, 07/15/04, 07/21/05, 05/18/06, 04/19/07, 06/19/08, 05/28/09, 04/22/10, 03/17/11, 03/15/12, 06/19/14, 08/20/15, 10/20/16, 10/19/17, 06/21/18, 12/20/18, 06/20/19, 08/20/20, 04/15/21, 09/16/21, 05/19/22, 05/18/23, 10/17/24, 06/26/25, 06/18/26

Date	Summary of Changes

06/18/26	• Annual review; new criteria added to allow dorsal column spinal cord stimulator for painful diabetic peripheral neuropathy.
06/26/25	• Annual review, policy intent unchanged. Revised conservative treatment criteria.
01/01/25	• Summary of changes tracking implemented.
11/15/01	• Original effective date