April 22, 2022

RE: LCD Reconsideration Request - First Coast Service Options L36035 SPINAL CORD Stimulation for Chronic Pain and Novitas L35450 SPINAL CORD Stimulation (Dorsal Column Stimulation)

Dear First Coast Service Options and Novitas Medical Directors and Medical Affairs Team:

Medtronic is a global leader in medical technology, services, and solutions. The company offers a variety of products and therapies across all of the Medicare Administrative Contractor (MAC) jurisdictions to serve our patients, including FDA-approved therapies in spinal cord stimulation (SCS) for the treatment of chronic, intractable pain for patients with inadequate pain relief or intolerable side effects from medication who have failed or could not tolerate more conservative treatments. We appreciate the critical role MACs hold in outlining coverage criteria and facilitating access to critical therapies for Medicare beneficiaries. Thank you for the opportunity to present this local coverage determination (LCD) reconsideration request to First Coast Service Options (FCSO) and Novitas Solutions, Inc.

Recently, the U.S. Food and Drug Administration approved Medtronic’s Intellis™ rechargeable neurostimulator and Vanta™ recharge-free neurostimulator on January 21, 2022, for the treatment of chronic pain associated with diabetic peripheral neuropathy (DPN) of the lower extremities. This approval not only validates the safety of this treatment but comes after more than 50 years of broad payer coverage for this well-studied and well-established therapy for the treatment of a variety of chronic pain diagnoses.

As a result of the indication expansion for SCS, Medtronic is submitting a formal LCD reconsideration request for the Novitas SPINAL CORD Stimulation (Dorsal Column Stimulation) LCD (L35450) and FCSO SPINAL CORD Stimulation for Chronic Pain LCD (L36035), and the associated Local Coverage Articles (LCAs) (A57023, A57709) to include diabetic peripheral neuropathy and forthcoming FDA approved indications as covered conditions. In this request, we outline the Level 1 clinical evidence that supports the efficacy of SCS for the treatment of chronic pain due to DPN.

Additionally, we would like to include an “evergreen” clause in the reconsideration request for FCSO and Novitas to accommodate updates to the LCD and LCA respectively for FDA approved indications and resulting diagnosis codes that support the clinical benefit of SCS for Medicare beneficiaries. Such an evergreen clause could be added as proposed: “FCSO and Novitas may add or update additional diagnosis for future LCDs and/or LCAs without a formal reconsideration to accommodate new indications or conditions when the evidence demonstrates clinical benefit.” Similar language has been used by CMS in the NCD for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33).

Statutorily-Defined Medicare Benefit Category

We do not request any change to the applicable physician services, facility (outpatient hospital, inpatient hospital, and ambulatory surgery center) services, and prosthetic devices for the Medicare benefit
category which LCDs L35450 and L36035 and National Coverage Determination (NCD) 160.7 currently provide coverage under.

**Requested LCD Language to Add Under “Limitations” (Novitas L35450 Only)**

We request the addition of patient selection criteria in the limitations section of Novitas LCD L35450 only to underscore that this is not a first-line chronic pain treatment and to ensure the appropriate screening and patient education have occurred prior to implantation.

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

Patients must have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation). Documentation of the history and careful screening must be available in the patient chart if requested. Patients being selected for a trial:

- Must not have active substance abuse issues.
- Must undergo proper patient education, discussion, and disclosure including an extensive discussion of the risks and benefits of this therapy.
- Must undergo appropriate psychological screening”

The proposed patient selection criteria above originates from LCD L35136 and corroborates what a combined analysis by Medtronic of two randomized controlled trials (RCTs) shows. Specifically, that patient selection for SCS therapy and its subsequent success is contingent upon its use following careful evaluation and selection after more conservative attempts having been tried and failed. In the case of combined analysis or DPN RCT data, these diabetic patients suffered from pain for more than 6 years. The combined analysis not only validated the efficacy of the therapy for DPN of the lower extremities but only after years of unsuccessful attempts to manage the patient’s pain.

**Requested LCD Language to Add Under “Covered Indications”**

We request the addition of two new sections to the current Novitas and FCSO LCD Coverage Guidance Covered Indications subsections to support the appropriate use of SCS to treat diabetic peripheral neuropathy and to accommodate the appropriate access, where medically necessary, for future indications that are deemed safe and effective per FDA approval.

- “To treat intractable pain associated with diabetic peripheral neuropathy (DPN) of the lower extremities.

FCSO/Novitas may add or update additional diagnosis for future LCAs without a formal reconsideration to accommodate new indications when the evidence demonstrates clinical benefit.”

Our request is predicated in part on the results of three RCTs that compared SCS therapy to conventional medical management in patients with refractory painful diabetic peripheral neuropathy. Two of these studies evaluated the use of traditional SCS programming, pulse frequencies that range from 2 Hz to 1200 Hz, while the remaining study evaluated 10 kHz SCS therapy. Not only did the 2 level 1 RCTs focusing on traditional programming show an odds-ratio, which is the likelihood of success if a treatment is given in relation to the likelihood of a success if a treatment is not given, of 17 times greater odds of
success in favor of SCS, but it indicates similar responder rates, 70%, across all RCTs regardless of programing with either traditional or 10 kHz therapy. Furthermore, the body of evidence shows 86% of subjects had significant pain relief after 1 year of treatment and 80% of still used SCS to manage their pain through 5 years.

**Requested Codes to Add Under the Corresponding LCAs**

The following diagnosis codes for DPN support medically necessary conditions for treatment with SCS therapy. The totality of the evidence supports reconsideration of these diagnosis codes for addition to the Novitas and FCSO LCAs to ensure consistent Medicare beneficiary access to SCS for the treatment of DPN across MAC jurisdictions.

**Requested LCA Codes to Add Under ICD-10-CM Codes that Support Medical Necessity Group 1 (FCSO) / Group 2 (Novitas)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E08.42</td>
<td>Diabetes mellitus due to underlying condition with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E09.42</td>
<td>Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E10.42</td>
<td>Type 1 diabetes mellitus with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E11.42</td>
<td>Type 2 diabetes mellitus with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E13.42</td>
<td>Other specified diabetes mellitus with diabetic polyneuropathy</td>
</tr>
</tbody>
</table>

**Justification for Addition: SCS as a treatment for Diabetic Peripheral Neuropathy: Clinical Evidence**

DPN is a debilitating and progressive neurological disorder with minimal effective treatment options for patients today. An internal Medtronic evaluation of published and non-published data estimated a prevalence of 770,000 and an annual incidence of 48,000 for moderate to severe, refractory DPN in the US. Over time, DPN can have a significant impact on both quality of life and functional ability. According to retrospective claims research by Mehra et al and Sadosky et al, patients with painful DPN had significantly greater healthcare resource utilization and costs than patients with non-painful DPN and patients with diabetes only, driven by outpatient costs and pharmacy costs. In fact, incremental annual commercial payer cost of treatment of a patient with severe painful DPN vs non-painful DPN has been calculated as $30,755 vs. $12,492. Moreover, the loss of sensation that can come with DPN impairs the ability of the patient to notice slowly healing sores which creates the potential for infection and limb loss. Yang et al found that patients may be treated with medications, but they are often only partially effective and can result in serious side effects, leading to medication therapy abandonment in up to 50% of treated patients.

Two independent randomized controlled trials (de Vos et al and Slangen et al) – one of a Medtronic device and one of a competing similar product - show patients with chronic DPN, with moderate to severe symptoms and refractory to other treatments, achieve significant pain relief when treated with SCS with conventional medical management (CMM) compared to CMM treatments alone.
Inclusive of these two studies, 70% of patients receiving treatment with SCS for chronic pain associated with DPN experienced treatment success compared to 6% of patients receiving CMM alone. Those treated with SCS experienced a 53% average reduction in pain, compared to 0% among patients receiving CMM alone. A recent meta-analysis by Duarte et al of those two studies also showed a significant improvement in health-related quality of life in patients treated with SCS compared to those receiving only conventional treatments. A long-term analysis by van Beek et al of patients treated in one of the studies using Medtronic SCS technology showed 80% of patients treated with SCS continued to use their devices at five years to treat their pain.

Below we provide a detailed overview of the three Level 1, randomized studies of SCS use in a DPN population available today:

**Slangen et al (2014)** conducted a multicenter, randomized, open-label, controlled trial to evaluate the effect of SCS therapy in patients with painful diabetic peripheral neuropathy (PDPN). Eligible patients had moderate to severe PDPN in the lower limbs refractory to conventional treatment. Study participants were randomized 3:2 to receive treatment with SCS and best medical treatment (BMT) or BMT alone. Patient demographics in the SCS group (n = 22) were: 15 men and 7 women; average age, 57.1 (standard deviation, 12.4) years. Patient demographics in the BMT group (n = 14) were: 9 men and 5 women; average age, 56.5 (standard deviation, 8.0) years. In the SCS group, 17 patients successfully completed trial stimulation and were implanted with a permanent SCS system; 4 patients had a negative trial stimulation, and 1 patient died after attempted trial stimulation due to a subdural hematoma. Follow-up visits were scheduled at 3 and 6 months postimplant.

**Efficacy outcomes:** The primary outcome was the proportion of patients who achieved treatment success at 6 months, defined as 1) ≥ 50% pain relief (numeric rating scale, [NRS]) for 4 days during daytime or nighttime or 2) a score ≥ 6 (“much improved” or “very much improved”) on the Patient Global Impression of Change (PGIC) scale for pain and sleep. Secondary outcomes included pain severity, pain interference with daily life, pain characteristics, health-related quality of life, pain interference with sleep, sleep quality/quantity, mood, and medication use. Data from an intent-to-treat (ITT) analysis related to the primary outcome are summarized in the table below.

<table>
<thead>
<tr>
<th>Primary Outcome (ITT Analysis)</th>
<th>SCS+BMT Group (n = 22)</th>
<th>BMT Group (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with treatment success at 6 months, n (%)</td>
<td>13 (59%)</td>
<td>1 (7%)**</td>
</tr>
<tr>
<td><strong>NRS ≥ 50% Pain Reduction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daytime, n (%)</td>
<td>9 (41%)</td>
<td>0 (0%)***</td>
</tr>
<tr>
<td>Nighttime, n (%)</td>
<td>8 (36%)</td>
<td>1 (7%)**</td>
</tr>
<tr>
<td><strong>PGIC ≥ 6</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain, n (%)</td>
<td>12 (55%)</td>
<td>0 (0%)***</td>
</tr>
<tr>
<td>Sleep, n (%)</td>
<td>8 (36%)</td>
<td>0 (0%)*</td>
</tr>
</tbody>
</table>

Adapted from Slangen et al (2014) Table 2; between-group (SCS vs BMT) p-values: *p < 0.05; **p < 0.01; ***p < 0.001

**BMT =** best medical treatment, **ITT =** intent-to-treat, **NRS =** numeric rating scale, **PGIC =** Patient Global Impression of Change, **SCS =** spinal cord stimulation

**de Vos et al (2014)** conducted a multicenter, randomized, open-label, controlled trial to assess pain relief with SCS therapy in patients with painful diabetic neuropathy (PDPN). All patients had pain in their lower extremities that was refractory to conventional medical management (CMM). Patients were randomized 2:1 to treatment with SCS and CMM (SCS group) or with CMM alone (CMM group). Patient
demographics in the SCS group (n = 40) were 25 men and 15 women; average age, 58 (standard deviation, 11) years. Patient demographics in the CMM group (n = 20) were 13 men and 7 women; average age, 61 (standard deviation, 12) years. In the SCS group, 37 patients received a permanent SCS system; 3 patients did not have a successful trial. Follow-up visits were scheduled at 1, 3, and 6 months postimplant. After 6 months, those in the CMM group could cross over to the SCS group if they did not experience adequate pain relief.

**Efficacy outcomes:** The primary outcome of the study was the percentage of patients with > 50% pain reduction at 6 months; pain was evaluated using a visual analog scale (VAS). Secondary outcomes included average reduction in pain intensity, pain characteristics, quality of life, medication use, and patient global impression of change (PGIC). Primary outcome results (intent-to-treat [ITT] analysis), along with mean VAS scores at baseline and 6 months are summarized in the table below.

<table>
<thead>
<tr>
<th>Primary Outcome (ITT Analysis)</th>
<th>SCS+CMM Group (n = 40)</th>
<th>CMM Group (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with &gt; 50% reduction at 6 months, n (%)</td>
<td>25 (63%)†</td>
<td>1 (5%)*</td>
</tr>
<tr>
<td>Mean VAS Scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (SD)</td>
<td>73 (16)</td>
<td>67 (18)</td>
</tr>
<tr>
<td>6 months (SD)</td>
<td>31 (28)**</td>
<td>67 (21)*</td>
</tr>
</tbody>
</table>

Adapted from De Vos et al (2014) Table 2; *between-group p-value < 0.001; **within-group p-value < 0.001
CMM = conventional medical management, ITT = intent-to-treat, SCS = spinal cord stimulation, SD = standard deviation, VAS = visual analog scale
†Number calculated using the number of patients randomized to the SCS study group (n = 40) and the number of patients in the SCS study group with > 50% pain reduction (n = 25) at 6 months. The publication itself (de Vos et al [2014]; Table 2) reported a “> 50% pain reduction n (%)” of “25 (60%)” for the SCS study group (n = 40; randomized patients) at 6 months.

Petersen et al (2021) conducted a multicenter, open-label SENZA-PDN randomized controlled trial to evaluate the effect of 10-kHz SCS in patients with painful diabetic neuropathy (PDN).8 Eligible patients had PDN in the lower limbs refractory to conventional therapy. Study participants were randomized 1:1 to receive treatment with 10-kHz SCS plus conventional medical management (CMM) or CMM alone. Patient demographics in the 10-kHz SCS group (n = 113) were: 70 men and 43 women; mean age, 60.7 (standard deviation, 11.4) years. Patient demographics in the CMM group (n = 103) were: 66 men and 37 women; mean age, 60.8 (standard deviation, 9.9) years. Six patients failed trial stimulation and a total of 90 patients underwent permanent implant. Follow-up occurred at 3 and 6 months; data collection was planned for a total of 24 months. At 6 months, patients could cross over to the opposite group if they had insufficient pain relief (< 50% improvement in pain), were dissatisfied with their treatment, and were able to proceed according to their physician.

**Efficacy outcomes:** The primary outcome of the study was the percentage of patients with ≥ 50% pain relief without “worsening of baseline neurological deficits” at 3 months; pain was evaluated using a visual analog scale (VAS). Secondary outcomes included pain (VAS), neurological exam, health-related quality of life, and hemoglobin A1C (HbA1C). Regarding the primary outcome assessment, the authors stated, “In the CMM group, 5 of 94 patients (5%) met the composite primary end point of 50% or more pain relief using the VAS without observed deterioration on neurological examination compared with 75 of 95 in the 10-kHz SCS plus CMM group (79%; difference, 73.6%; 95% CI, 64.2-83.0; P < .001).” Additionally, the authors stated, “Sensitivity analyses considered varying assumptions for missing data with no effect on the conclusion that the treatment effect for 10-kHz SCS plus CMM was superior to CMM alone (eTable 1
in Supplement 3).” A summary of the information presented in eTable 1, “Primary end point sensitivity analysis results” from Supplement 3 is provided below.

<table>
<thead>
<tr>
<th>Population</th>
<th>Description</th>
<th>CMM</th>
<th>10 kHz SCS+CMM</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Per protocol</td>
<td>5/94 (5.3%)</td>
<td>75/87 (86.2%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>2</td>
<td>ITT known status 10 kHz SCS</td>
<td>5/94 (5.3%)</td>
<td>75/95 (78.9%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>3</td>
<td>ITT worst case for 10 kHz SCS LTF</td>
<td>5/94 (5.3%)</td>
<td>75/98 (76.5%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>4</td>
<td>ITT worst case all missing 10 kHz SCS</td>
<td>5/94 (5.3%)</td>
<td>75/112 (67.0%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>5</td>
<td>ITT worst 10 kHz SCS/best CMM case</td>
<td>12/103 (11.7%)</td>
<td>75/113 (66.4%)</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

Adapted from the Supplemental Online Content for the Petersen et al (2021) publication (eTable 1 in Supplement 3). Authors stated, “Subjects who did not complete the neurological assessment at 3 months were excluded from primary endpoint analysis of populations 1-4 for CMM (n = 2) and populations 1-3 for 10 kHz SCS+CMM (n = 1).”

CMM = conventional medical management, ITT = intent-to-treat, LTF = lost to follow-up, SCS = spinal cord stimulation

**Definition of DPN and Overview of Clinical Therapy**

Painful Diabetic Peripheral Neuropathy typically presents in patients with a history of poor glycemic control via bilateral pain in the feet and lower legs. This pain, typically stabbing or burning in nature, can progress and lead to numbness. The pain frequently starts in the toes and progresses proximally in a stocking and glove pattern with increased pain often during sleep. Furthermore, the loss of sensation, as noted before, can impair the ability of the patient to notice slow healing sores which can lead to potential infection and limb loss. It is important to note that SCS has only been studied and shown effective in DPN of the lower extremities.

Before a patient is considered for SCS therapy, there are a number of criteria that must be satisfied before they can be considered. Not only does the patient need to be diagnosed with painful neuropathy but consideration must be given to contraindications and comorbidities as well as the use of pregabalin or gabapentin, tricyclic antidepressants as well as serotonin-norepinephrine reuptake inhibitors. If pain control remains inadequate following these therapies and after weighing any contraindications, the patient can then be considered for a possible SCS trial.

SCS therapy is a treatment for chronic pain through the modulation of the nerves that help control pain. The therapy is delivered by sending electrical pulses from a neurostimulator through a lead to the spinal cord to modulate pain signals. Before permanent implantation is considered, the patient undergoes a trial period with a device, typically for one week at which time, if successful, can be followed by a complete neurostimulation system implantation. Again, before a trial and permanent implantation is performed, the patient must be refractory to best efforts to manage their diabetes, refractory to medication management as well as non-inceptive therapies, be a good surgical candidate and demonstrate they have the ability to manage SCS therapy. Based on these considerations, clinicians can recommend patients for this therapy.

**Historical Background of SCS and Current Novitas and FCSO LCDs**

CMS has a long-standing NCD (160.7) supporting coverage of Spinal Cord Stimulation (SCS) for Medicare patients suffering from chronic intractable pain that has been refractory to other treatments. DPN appears to fall within the same category of patients referenced in this NCD who suffer from chronic intractable pain, as it relates to a subset of patients with pain caused by diabetic peripheral neuropathy.
Unfortunately, differences in LCDs and LCAs across the MACs are creating significant inequities in access to SCS therapy for CMS beneficiaries with DPN, notably those with procedures that would be performed in the Novitas and FCSO MAC jurisdictions.

We respectfully request an expeditious LCD reconsideration request for the Novitas LCD (L35450) and FCSO LCD (L36035), and associated LCAs (A57023,A57709) to include diabetic peripheral neuropathy as a covered indication along with language to ensure appropriate access to future covered indications where medically appropriate for Medicare beneficiaries.1-4

Further, FCSO and Novitas do not list DPN diagnoses as Group 1 or Group 2 codes in their LCAs (A57709, A57023).3,4 However, both the FCSO and Novitas’ LCAs currently list unspecified neuropathy diagnosis codes (see Table 1 below). Addition of the more specific diagnosis codes for diabetic peripheral neuropathy (polyneuropathy, Table 2) to the LCA are more appropriate given the ICD-10-CM diagnosis coding available. Without the coding edit to the LCA we fear there will be confusion among providers on how to appropriate code and bill for patients with DPN, leading to disparities in coverage among Medicare beneficiaries.

Table 1. Current FCSO (Group 1 Codes) and Novitas (Group 2 Codes) for Unspecified Neuropathy

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G56.90</td>
<td>Unspecified mononeuropathy of unspecified upper limb</td>
</tr>
<tr>
<td>G56.91</td>
<td>Unspecified mononeuropathy of right upper limb</td>
</tr>
<tr>
<td>G56.92</td>
<td>Unspecified mononeuropathy of left upper limb</td>
</tr>
<tr>
<td>G56.93</td>
<td>Unspecified mononeuropathy of bilateral upper limb</td>
</tr>
<tr>
<td>G57.90</td>
<td>Unspecified mononeuropathy of unspecified lower limb</td>
</tr>
<tr>
<td>G57.91</td>
<td>Unspecified mononeuropathy of right lower limb</td>
</tr>
<tr>
<td>G57.92</td>
<td>Unspecified mononeuropathy of left lower limb</td>
</tr>
<tr>
<td>G57.93</td>
<td>Unspecified mononeuropathy of bilateral lower limb</td>
</tr>
</tbody>
</table>

Table 2. Proposed Additions to Group 1 Codes (FCSO) & Group 2 Codes (Novitas) for Peripheral Diabetic Neuropathy

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E08.42</td>
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<tr>
<td>E13.42</td>
<td>Other specified diabetes mellitus with diabetic polyneuropathy</td>
</tr>
</tbody>
</table>

SCS has been commercially available and broadly covered for over 50 years for patients with chronic intractable pain. An implantable spinal neurostimulation system is not considered until the patient is evaluated to confirm that the symptoms are chronic with a duration of at least 3-6 months with the average patient presenting with symptoms for more than 6 years. The pain, rated with a score of ≥5 (Numeric Rating Scale 0-10), is also intractable with the patient having to have attempted treatment with more conservative therapies without success such as glycemic control, pain medications, physical therapy, and topicals, all without sufficient relief and/or intolerable side effects. Furthermore, there are treatment algorithms in place for documenting medical necessity and appropriate utilization. The national CMS policy requirement for prior authorization provides an opportunity to review medical
necessity in advance of the implant, and SCS trials provide better visibility to treatment for pain improvement.

Our Request

We respectfully request FCSO and Novitas reconsider their respective LCDs (L36035 and L35450) and corresponding LCAs (A57709 and A57023) with the aforementioned language and diagnosis codes that support diabetic peripheral neuropathy to ensure that, where medically appropriate, your beneficiaries and providers have consistent access to this therapy. To ensure timely accommodation for the additional clinical benefits of SCS for new indications and diagnosis codes, we request FCSO/Novitas may add or update additional diagnosis for future LCAs without a formal reconsideration to accommodate new indications when the evidence demonstrates clinical benefit.

We believe the evidence presented strongly supports our request for updated LCDs for both FCSO and Novitas. Should you have any questions as you review this material or if you would like additional information, please contact me by phone at 651-242-0488 or via email at john.p.joseph@medtronic.com.

Sincerely,

John Joseph
Payer Relations Manager
Neuromodulation

Enclosures:

1. FDA Approval Letter
2. Bibliography of Peer-Reviewed Studies of SCS Therapy for DPN
3. Full Texts of Studies Referenced
References

Diabetic Peripheral Neuropathy

Bibliography for Reimbursement

SEARCH CRITERIA: This bibliography was established by searching PubMed and Embase for articles published in English, on humans, that contained terms for spinal cord stimulation and painful diabetic neuropathy. We also assessed review papers for content and references to provide a comprehensive literature search. The search excluded expert opinion, non-systematic reviews, bench data, conference proceedings, and single-patient case reports. Articles listed were chosen to be representative of Medtronic labeling for SCS for chronic pain, including diabetic peripheral neuropathy; articles deemed to represent off-label use of the therapy were excluded from the bibliography.

This bibliography is not exhaustive. The articles selected for inclusion in the bibliography met the stated search criteria and were deemed relevant to aid in the payer decision-making process.

Randomized Controlled Trials


Full text: https://care.diabetesjournals.org/content/37/11/3016.long


Full Text: https://care.diabetesjournals.org/content/38/9/e132.long


Full Text: https://care.diabetesjournals.org/content/41/1/32.long


Full Text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4893357/


Full text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8022268/


Meta-Analyses


Prospective Studies


**Healthcare Utilization in Diabetic Peripheral Neuropathy**


**Reviews**
