Comments regarding HTA Draft Report: Spinal Cord Stimulation

From: Judith A. Turner, Ph.D.
Professor, Dept. of Psychiatry & Behavioral Sciences and Dept. of Rehabilitation Medicine
University of Washington School of Medicine
Seattle, Washington

Date: July 14, 2010

I would like to call attention to several inaccuracies in the Draft Report regarding the prospective cohort study I conducted along with my co-investigators William Hollingworth, Bryan Comstock, and Richard Deyo.

On page 75 of the Draft Report, it is stated that "significantly more patients in the SCS group achieved the alternate definition of success (leg pain relief $\geq$ 30%, RDQ improvement of $\geq$ 5 points, and less than daily opioid usage) at six months compared with the PC and UC groups: SCS versus PC (22% versus 5%, respectively; P = .03); SCS versus UC (22% versus 5%, respectively; P = .01)". This statement is not accurate. The authors of the draft report mis-read our section 3.3 in our published *Pain* article. In fact, at six months, more SCS patients, compared to the Pain Clinic and Usual Care groups, showed clinically meaningful improvement using two alternate definitions on the Roland Disability Questionnaire (RDQ), **not on the alternate composite success measure**. This difference was observed using the two alternate definitions of clinically meaningful improvement on the RDQ: (1) $\geq$5-point improvement (22% in the SCS group versus 5% each in the Pain Clinic and Usual Care groups) and (2) $\geq$ 30% improvement (16% in the SCS group versus 5% Pain Clinic and 3% Usual Care). **Only 4% of the SCS patients achieved success on the alternate composite outcome** (5-point RDQ improvement, 30% leg pain improvement, and less than daily opioid use) at six months. The authors also incorrectly state on page 76 of the draft report that "significantly more SCS patients achieved leg pain relief of at least 30% compared with those in the PC or UC groups at six months: SCS versus PC (16% versus 5%, respectively; crude absolute benefit increase, 11%; P = .03); SCS versus UC (16% versus 3%, respectively; crude absolute benefit increase, 13%; P = .01)." In fact, as we report in section 3.3 of our *Pain* article, the 16% versus 5%, and 16% versus 3%, rates are for $\geq$30% improvement **in RDQ score, not leg pain**.

The draft report also implies that we only analyzed data from patients with complete data from all follow-up assessments. In fact, for each follow-up timepoint (6, 12, and 24 months), we analyzed all available data at that timepoint (n=155 at 6 months, 148 at 12 months, and 138 at 24 months).

A minor point: On page 76, the draft report says that we obtained VAS pain scores. We did not. All pain ratings were made using numerical rating scales, not visual analogue scales.

It is stated on page 76 that there were no significant differences between treatment groups in medication usage, with the exception of anticonvulsant use, which was higher in the SCS

than the PC, but not the UC, group. At six months, fewer SCS patients reported less than daily opioid use [12% SCS versus 34% Pain Clinic (P= 0.04) and 27% Usual Care (ns)]. The difference in anticonvulsant use was observed only at 24 months, and the P-value for the comparison with the Usual Care group was .06. Also, the numbers for anticonvulsant use in the draft report are wrong. The correct numbers are 14/43 in the SCS group and 2/34 in the PC group at 24 months.

I find the draft report's term of "per-protocol" analysis to be confusing. I would instead recommend a more descriptive term, such as "analyses comparing patients who received a permanent stimulator versus patients who received some pain clinic treatment."

On page 76, it is stated that there were differences in rates of surgery and use of other therapies at two years. In fact, these differences were reported **for one year, not two years** of follow-up.

Finally, there are a number of errors in the section reporting our study in Supplemental Table 3:

a. On page 40 in the Function column, the wording should be "improvement", not "increase" in RDQ score. This mistake is repeated on page 44.
b. In the medication usage column, **it is not at all accurate to report these numbers as "decrease in daily opioid dosage." The rates reflect the percent of patients who reported that they used opioid medication on a less than daily basis.** For example, 21% of patients in the SCS group said that they used opioid medications on a less than daily basis; to state this in another way, 79% said that they used opioids on a daily basis. (The same error is repeated on page 43-the wording should be changed there as well.)
c. The definition of the primary outcome in the last column is incorrect and should be changed to the exact definition as provided in our published article in *Pain.*
d. On page 40, the wording in the first column at the bottom of the page regarding "per protocol analysis SCS n=22 and PC n=22" should be removed as the data in the corresponding columns are for the entire group, not these two subgroups.
e. The footnote to this table states that for the time loss/pension data shown on page 43, the percents do not equal the patient ratios reported. In fact, the percents, numerators and denominators reported in Table 5 in our article in *Pain* are correct, but the authors of the draft report substituted incorrect denominators in their table. The correct denominators, as shown in Table 5 in the *Pain* article, are n=51 for the SCS group, n=39 for the Pain Clinic group, and n =68 for the Usual Care group. As indicated in our Table 5, these data are from the administrative database rather than from subject self-report and therefore we have complete data for study participants for these variables.

I appreciate the opportunity to correct these points in the draft report. Please let me know if you have any questions about my comments.

Boston Scientific
Delivering what's next.

July 15th, 2010

Brian Budenholzer, MD
Health Technology Clinical Committee Chair
Washington State Health Technology Assessment Program
PO Box 42712
Olympia, WA 98504-2712

RE: Comments on HTA Draft Report: Spinal Cord Stimulation

Dear Mr. Budenholzer:

Boston Scientific Neuromodulation appreciates the opportunity to comment on the HTA Draft Report: Spinal Cord Stimulation (SCS) by the Washington Health Technology Assessment Program. We commend the significant undertaking to review the body of clinical evidence on SCS, but we are concerned that the draft report contains inaccuracies that will result in a skewed assessment which could negatively affect the availability of appropriate SCS therapy for chronic pain patients.

As a worldwide developer and manufacturer of medical devices for over 30 years, Boston Scientific has advanced the practice of less-invasive medicine by providing a broad and deep portfolio of innovative products, technologies and services across a wide range of medical specialties. The company's products help physicians and other medical professionals improve their patients' quality of life by providing alternatives to surgery; alternatives that also significantly improve the productivity of health care delivery by reducing hospital stays and averting downstream medical treatment costs. Boston Scientific's introduction of the world's first rechargeable SCS system is an example of our commitment to pioneer less-invasive medical advancements

SCS is a broadly accepted treatment for chronic intractable pain that is supported by a longstanding positive Medicare National Coverage Determination (NCD), and is a covered benefit under almost all commercial health insurance and workers' compensation plans in the nation. It has been shown to be both clinically effective and cost-effective by multiple randomized trials, [1-5] a 2008 evidence-based technology appraisal by NICE in the United Kingdom, [6] and evidence-based clinical practice guidelines published by national medical societies including the American Society of Anesthesiology (ASA) as recently as October 2009. [7]

HTA Draft Report Recommendations

Boston Scientific appreciates the ability to work with the Washington Health Technology Assessment Program in supporting the accuracy and appropriateness of this assessment and

we welcome the opportunity to provide the following feedback and our prioritized recommendations.

I. Mortality Strength of Evidence

Boston Scientific is concerned that the response to Key Question 2.3 (page I6) which states that the strength of evidence regarding mortality is "High", could be misconstrued by some to inappropriately conclude that there is a significant mortality risk with SCS therapy. For other questions it is more clear what the strength of evidence is regarding. For example, the response to Key Question 1.1 (page I5) states, "There is moderate evidence from three small randomized controlled trials that SCS is superior to conventional therapies..." In this statement, it is very clear that there is moderate evidence supporting SCS superiority over conventional therapies. BSC requests that similar clarity be provided for Key Question 2.3 by adding the statement, "There is a high level of evidence to suggest that SCS therapy does not increase mortality risk".

While it is not stated clearly, we assume this was the conclusion based on the fact that the report states numerous times that "no deaths were attributed to SCS" and concludes "In no case was the cause of death attributed to the SCS device or procedure for implanting or revising the device". This conclusion is in congruence with the long history of the safe application of SCS therapy.

II. Inclusion of a Level of Evidence (LoE) III Study in Evaluating Efficacy and Effectiveness

In evaluating efficacy or effectiveness of SCS therapy, four studies were chosen. Three of these studies were Level of Evidence (LoE) II and one was LoE III (Turner 2010). In evaluating outcomes, six studies were chosen. One of these studies was LoE I and five studies were LoE II.

Boston Scientific questions the inclusion of the LoE III study for evaluating efficacy or effectiveness. By definition, a LoE III study represents a moderate or poor cohort. It seems the inclusion of this study could have the unintended consequences of skewing the efficacy and effectiveness findings contained in the draft report.

More concerning, not only was this LoE III study (Turner 2010) included in evaluating efficacy or effectiveness, but at times was the significant or even the sole study leading to the conclusion. For example, in assessing effectiveness under question 1.2, Turner 2010 was the sole study used in the report's conclusion. BSC recommends that Turner 2010 be limited to only appropriate questions.

Specifically, we request that Turner 2010 be removed from assessments for questions evaluating efficacy or effectiveness. Among other implications, this would result in changing the strength of evidence for question I.2 from "Low" to "No evidence". Turner 2010 should still be considered in assessing question 3.3, "*"What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations – 3rd party coverage?"*

III. Inappropriately Aggregating Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Data

In this draft report, SCS clinical studies treating both FBSS and CRPS were aggregated. However, FBSS and CRPS are separate and unique indications with the possibility of vastly differing efficacy, effectiveness, safety and cost-effectiveness. Aggregating the evidence for two very different conditions can significantly skew the results. BSC recommends that SCS therapy for FBSS and CRPS be evaluated separately on their own merit.

Recommendation Summary

- BSC recommends that the statement, "There is a high level of evidence to suggest that SCS therapy does not increase mortality risk" is added to question 2.3.
- BSC requests that Turner 2010 be removed from assessments for questions evaluating efficacy or effectiveness. Among other implications, this would result in changing the strength of evidence for question 1.2 from "Low" to "No evidence".
- BSC recommends that SCS therapy for FBSS and CRPS be evaluated separately.

Thank you for the opportunity to comment on your draft HTA report. We look forward to discussing our perspective with you, and want to encourage strong transparency and visibility in providing continued opportunities to participate in the review process.

Sincerely,

Matt Gunderman
Director, Health Economics and Reimbursement
Boston Scientific Neuromodulation

---

[1] North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005;56:98-106; discussion 106-7.

[2] Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008 Oct;63(4):762-70; discussion 770.

[3] Kumar K, Taylor RS, Jacques L, Eldabe S, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomized controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179-188.

[4] Kemler MA, DeVet HC, Barendse GA, van Den Wildenberg FA, van Kleef M. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol 2004;55:13-8.

[5] Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 2000;343:618–24.

[6] Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation.Health Technol Assess 2009;13(17). http://www.hta.ac.uk/1677.

[7] American Society of Anesthesiologists. Clinical practice guidelines for chronic pain management. October 2009.

Medtronic, Inc.
Neuromodulation
7000 Central Avenue NE
RCE 395
Minneapolis, MN 55432
www.medtronic.com

tel 763-526-8193
fax 763-526-8373
william.fehrenbach@medtronic.com

N. William Fehrenbach, MSSW
Reimbursement Director

July 16, 2010

Doug Porter
Washington State Health Care Authority
676 Woodland Square Loop SE
Lacey, WA 98503
portejd@dshs.wa.gov

Leah Hole-Curry, JD
Director, Health Technology Assessment
676 Woodland Square Loop SE
Lacey, WA 98503
leah.hole-curry@hca.wa.gov

Re: Spinal Cord Stimulation Health Technology Assessment*: Draft Report*

Dear Mr. Porter and Ms. Hole-Curry:

We are writing on behalf of Medtronic Neuromodulation. Medtronic is the world's leading medical technology company, specializing in implantable therapies that alleviate pain, restore health, and extend life. Our implantable therapies include spinal cord stimulators. Our purpose for writing is to provide comments on the draft health technology assessment report as part of your public comment period, and to help Spectrum produce the most accurate, balanced and understandable evidence review possible. Our response includes comments aligned to each section of the report beginning with a summary of our main concerns. Thank you in advance for your consideration.

Main Concerns

- The data and methods used to inform the key question of safety **infer that there is a mortality concern** with SCS, which is inaccurate.
- **Efficacy and effectiveness are being analyzed separately**, which for good reason has not traditionally been done in other HTAs, including those completed for WA State on other therapies.
- **Observational data is unsystematically and selectively being used to address safety and effectiveness** of SCS. As such, a single cohort study in a sub-population is used as the sole source of evidence of effectiveness.
- It is widely acknowledged that the sub-population of **Workers' Compensation patients are different** than non-Workers' Compensation patients. They tend to have worse outcomes across various therapies and these data cannot be generalized to the non-Workers' Compensation population (Atlas SJ, et al. Spine (Phila PA 1976) 2007;32(18):2019-26; Carreon LY, et al. Spine (Phila PA 1976) 2010 [epub ahead of print]; Atlas SJ, et al. Spine (Phila PA 1976) 2010;35(1):89-97; and Atlas SJ, et al. Am J Ind Med 1996;29(6):584-9).
    - The Turner, et al. cohort study has significant limitations and may not be generalizable to other Workers' Compensation patients outside Washington State

- **The use of short, mid, and long-term timeframes is unsystematically applied** to therapeutic HTAs for WA State. When combined with the selective use of observational data, it allows the reader to conclude that there is little to no mid-term or long-term safety or effectiveness data.
- **Data from FBSS and CRPS patients were combined** in the draft report and no distinction was made between outcomes associated with one indication versus another. While both conditions may be included under the umbrella of chronic neuropathic pain, and there is even some debate in this regard, they are distinct disease processes, are associated with different signs and symptoms and should not be lumped together. Just as the clinical trials focused on one or the other indication, so too should this report to ensure clarity in its application. Further, as evidence is focused on one particular indication respectively, so too are various guidelines, with Low Back guidelines generally applying to FBSS, and Chronic Pain guidelines generally applying to CRPS. However, no distinction was made in the guideline review either, mixing guidelines for multiple indications, (including indications other than FBSS and CRPS which is clearly beyond the scope of this evidence review). This "mixed" evidence and guideline discussion is atypical and confusing when trying to make reasonable conclusions more broadly.
- The **Sheffield health technology assessment**, used as the basis of the NICE determination, recommends appropriate coverage for SCS for indications including FBSS and CRPS. NICE, as an organization, and its resulting technology assessment reports are highly respected and serve as a model for other HTAs and decision-makers throughout the world. This must be incorporated into the evidence report.

I. Comments on Appraisal and Background Section of Draft Report

Section 1.1 Rationale

- **On page 19**, the first sentence should read "…and in some cases, **spinal surgery**".

Section 1.2 Key Questions

- **On page 19,** for Key question #1, there is no definition of the patient population of interest. Please define the population or indications to include neuropathic pain or FBSS and CRPS.

Section 2.1 The condition: chronic neuropathic pain

- **On page 21**, last paragraph, FBSS and CRPS are not the most common neuropathic pain indications.

Section 2.4 *Technology and its Comparators*

- **On page 26**, please include a reference for the contraindications.
- **On page 26**, it states under contraindications to SCS that systems must be removed prior to exposure to strong electromagnetic interference such as MRI. For Medtronic implantable SCS systems, this is incorrect. If all of the instructions stated in Medtronic's *MRI and Spinal Cord Stimulation for Chronic Pain (Appendix B)* at http://professional.medtronic.com/therapies/spinal-cord-stimulation/mri-guidelines/index.htm are followed, MRI examinations of the head using an RF transmit/receive head coil may be safely performed. We respectfully request clarifying language be added that reflects same.

Section 2.5 *Clinical Guidelines*[1]

- **On page 26**, the draft report states that only eight guidelines provided specific guidance on SCS, which is inaccurate. Out of the 36 guidelines, there were also two additional guidelines found in this search published by the Work Loss Data Institute (the Official Disability Guidelines (ODG) Low

[1] Some of the relevant medical society and payer organization guidelines and health technology assessments may mention uses which are not FDA-approved for Medtronic products. It is not our intention to promote unapproved use. However, we could not provide a comprehensive response without their inclusion. For those addressing unapproved uses of SCS, some language has been redacted. The source documents in their entirety may be found via the adjoining web links in the Appendices.

Back and Pain chapters), which clearly provide guidance on the use of SCS and should be included. In order to ensure accuracy in the report these two guidelines and their positive recommendations regarding SCS should be included. **See Appendix #1.**

- **On page 27**, the recommendation statement for the ACOEM low back guideline fails to include an important footnote that allows for use of spinal cord stimulation. In order to ensure accuracy of the report, language from the asterisk should be added: "* *Spinal cord stimulators may be considered as a late or last resort for highly selected patients who have failed multiple other conservative treatments including a quality functional restoration program and who have had a forensic psychologic assessment (83 percent Panel agreement).*".
- **On page 27**, the NASS spinal stenosis guideline is included and is not relevant. The draft HTA report is focused on the evidence for indications such as FBSS and CRPS, which fall into the categories of FDA-approved indications. Spinal stenosis is completely separate from these approved indications and clearly outside the scope of this health technology assessment. Further, it is unclear, as was raised by Spectrum, whether the guideline is referring to SCS as only the term "electrical stimulation" was used and was not further defined. Reference to this NASS guideline should either be completely removed, or alternatively specificity should be added regarding what indication this is in reference too in order to best ensure appropriate and accurate consideration of same.
- **On page 28,** the Sanders, et al. guideline, which is negative for SCS, represents an individual hospital guideline that is not affiliated with or endorsed by any organization or society. It clearly does not meet the definitions required in law for consideration and should be removed from consideration.
- If the ODG guidelines are appropriately included and the NASS guidelines are removed, as they are beyond the scope of this HTA, nine guidelines remain, of which, eight include positive recommendations for SCS, including the limited use allowed by ACOEM. If reference to Sanders is appropriately removed, there are eight guidelines, of which, all eight include positive recommendations for SCS.
- Although not currently included in NGC, there are three other specialty society guidelines that specifically include guidance for SCS. These are the American Society of Anesthesiology guideline, the American Pain Society guideline, and the American College of Occupational and Environmental Guideline Chronic Pain chapter. If these three additional guidelines are given consideration, there are 12 guidelines, of which, 11 include positive recommendations for SCS (as even the ACOEM chronic pain guideline provides some positive recommendation). **See Appendix #2.**
- **On page 27 and 28**, please include specific definitions of the level of evidence for each guideline so that it is clear to the reader what 1B or 1C mean, for example. It would be much more helpful to policymakers if the authors undertake a synthesized review i.e. the strength of the different methods used in guidelines/HTAs and a critique/explanation for the wide variation in recommendations.

Section 2.6 *Previous Systematic Reviews/Technology Assessments*

- **On page 29**, the Simpson, et al. systematic review is included in Table 1, however, the resulting technology assessment done by Sheffield for the National Institute for Health and Clinical Excellence (NICE) is not included. The final guidance from the NICE technology assessment should be reflected in the draft report. **See Appendix #3.**
- **On page 29**, for the Simpson systematic review (2009), clinical endpoints are incorrectly listed under the economic endpoints section. The reported cost/QALY information should be listed instead. This information can be found in Table 35 of the Simpson review and is recreated. **See Appendix #4.**

Section 2.7 *Medicare and Representative Private Insurer Coverage Policies*

- **On page 39**, the first paragraph would more accurately reflect the referenced CMS and BCBS coverage policies if the language was changed to state that payers "will provide coverage for SCS, as long as implantation of the device is used as a ***late or*** last resort (after all other treatment modalities have failed ***or are deemed inappropriate***)…"
- **On page 39,** a more comprehensive approach to reflecting private payer coverage policies for SCS, rather than selecting policies from perceived bellwether states, would be to examine in detail the

II. Comments Regarding the Evidence Section of the Draft Report

Section 3.1 Regarding *Methods of the Systematic Literature Review*

- Data from FBSS and CRPS patients were combined in the draft report and no distinction was made between outcomes associated with one indication versus another. While both conditions may be included under the umbrella of chronic neuropathic pain, they are distinct disease processes, are associated with different signs and symptoms and should not be lumped together. Just as the clinical trials focused on one or the other indication, so too should this report to ensure clarity in its application. The "indication" distinction is also important when guidelines are considered, as mentioned above, as certain guidelines only pertain to limited indications and should not be misunderstood. The diagnosis codes associated with CRPS include: 337.21, 337.22, 354.4, and 355.71, while the diagnosis codes associated with FBSS include: 722.83.
- Observational data is being included to inform the question on SCS effectiveness in the form of the Turner cohort study. Therefore, all observational data should be considered to inform short, mid, and long-term conclusions on effectiveness. Randomized controlled trials cannot provide the necessary longitudinal data nor does a single cohort study in the Workers' Compensation sub-population. It is interesting to note that another evidence report prepared by Spectrum for WA State on the use of artificial discs (another implanted device used in painful conditions) included the following statement: "In addition, 25 case series (LoE IV) were included to help address short and long term complication rates and secondary outcomes." Why are inconsistent methodologies being employed from one therapy to the next?
- **On page 44**, Table 3. Publication exclusions, cost-benefit, cost-effectiveness and cost utility studies are full economic evaluations and therefore should not appear in this exclusion section.

Section 3.2.3 Clinically meaningful improvement

- **On page 50**, clinically meaningful improvement is a conceptually important section. However, it is incomplete as it does not include the minimally important clinical differences (MCID) for other key outcomes in this area e.g. SF-36, ODI & EQ-5D. We respectfully request that this information be added. The PROCESS trial provides a good example of where differences in outcomes were not only statistically significant, but also clinically meaningful.
    - A 30% reduction in pain is clinically meaningful and is equivalent to categorical ratings of 'moderate relief' or 'much improved' *(Farrar JT, et al. Use of the cumulative proportion of responders analysis graph to present pain data over a range of cut-off points: making clinical trial data more understandable. J Pain Symptom Manage 2006; 31(4): 369–77*). In the PROCESS study ITT analysis at 6 months, significantly more patients in the SCS group (64%) experienced ≥ 30% pain reduction in their VAS leg pain score compared with the CMM group (18%) ($P < 0.0001$).
    - A difference of 3–5 points in the SF-36 is considered clinically relevant *(Samsa G, et al. Determining clinically important differences in health status measures: a general approach with illustration to the Health Utilities Index Mark II. Pharmacoeconomics 1999;15:141-55*). In the PROCESS study, the SCS group significantly improved in 7/8 domains of the SF-36 and between group differences of 9.5-21.8 points were observed at 6 months ($P<0.02$ to $P<0.001$).
    - For the Oswestry Disability Index, one stated MCID is 12.8 points (Copy A, et al. The Minimum Clinically Important Difference in Lumbar Spine Surgery Patients: A Choice of

III. Comments Regarding the Results Section of the Draft Report

Section 4.0 *Results*

Comments Pertaining to Key Question 1:

> ***1. What is the evidence of efficacy and effectiveness of spinal cord stimulation? Including consideration of:***
> ***a. Short-term and long-term outcomes***
> ***b. Impact on Function, Pain, quality of life***
> ***c. Other reported measures including: use of pain medications and opioids, return to work; intensity and duration of use***

- The disaggregating of data in the summary of efficacy and effectiveness allows the reader to conclude that there is low strength of evidence for mid-term efficacy, no evidence for long-term efficacy, and no evidence for mid-term and long-term effectiveness. The partitioning of outcomes data in this manner is atypical when compared with other systematic reviews and health technology assessments. Further it is unreasonable to assume for ***any*** technology that efficacy data for mid-term and long-term is readily available. Mid-term and long-term conclusions should be informed by a larger body of longitudinal, observational data. We respectfully request that data on efficacy and effectiveness be combined or all observational studies be allowed to inform effectiveness.
- While the draft report includes a discussion of some differences between RCTs and cohorts, it fails to include an important discussion about the generalizability of data. The Turner cohort study does not carry the same weight as a randomized control trial. Limitations to both study methodology and execution may limit its generalizability to other Workers' Compensation populations outside Washington State. Further, the Turner data cannot be generalized to a non-Workers' Compensation population. As such, in order to ensure accuracy, please reflect these points in various appropriate places on pages 77, 78, 79, 93, 94, 118, 119, and 120.
- If the inclusion of non-RCT data to assess efficacy/effectiveness was done to get a "real world" view of what happens to the technology, the authors of the draft report are overlooking an important point that one of the RCTs, the PROCESS study, was pragmatic in its design (e.g. compare SCS to usual care, use of patient related outcomes, have few inclusions/exclusions). Hence, there should be no reason why non-RCT data must be used to evaluate efficacy/effectiveness.
- **On page 51**, there is an error that should be corrected. The text states that all four studies for key question #1 received a level of evidence (LoE) grade of II. In fact, the Turner cohort study received a LoE grade of III, which was correctly stated on page 47 as well as in Appendix E of the draft report. In order to ensure accuracy please change this language.
- **On page 59**, there are a few statements regarding the PROCESS study that should be corrected. In paragraph two, it should state that both per protocol analysis **and** modified intention-to-treat analysis were performed. In paragraph three, it should state that intention-to-treat analysis was conducted on all outcomes at 6 months. At 24 months, a per protocol analysis was used for secondary outcomes.
- **On page 59**, the PROCESS study, as with the Kemler, et al. study, was criticized as having compared SCS to a treatment that already failed (i.e. conventional medical management or physical therapy). PROCESS was a pragmatic trial that was specifically designed to represent what would occur in real clinical practice for patients that are refractory to conservative treatment that that did receive SCS. Randomizing patients to a sham surgery may not be ethical and implanting all patients with SCS and blinding half to therapy (e.g. on versus off) is not possible given that patients can feel paresthesia.

- **On page 59,** paragraph 3, "thus this RCT compares SCS to an ineffective comparator". This is an inappropriate interpretation of what is, by definition, a comparator that represents usual care; Kemler, et al. clearly state they concealed allocation. The appropriate interpretation by the authors of this draft report should be that this criterion has been met.
- **On page 69**, "The primary limit of the study is the high cross-over rate". Can the authors explain this statement? Presumably they mean that cross-over at 6-months limits the ability to undertake an unbiased assessment of the relative effectiveness of SCS versus usual care after this point i.e. the longer term. The ethical and methodological issues associated with cross over are presented in the discussion of the Kumar RCT papers and should be referred to here.
- **On page 74**, the limitations of the Turner cohort study are discussed. It would be reasonable to include in this discussion that nowhere else in the literature is a composite measure of pain, disability, and medication use used to evaluate the effectiveness of SCS. Further, utilizing less than daily opioid use as an indicator of whether SCS is effective is not sensitive to cases where the patient significantly lowers their daily dose of opioids or moves to a less potent opioid.
- **On page 74,** the limitations of the Turner cohort study should include a discussion of how the results cannot be generalized to a non Workers' Compensation population. Further, the limitations are significant enough that it may not be generalizable to other Workers' Compensation populations outside of Washington State.
- **On page 77**, the discussion about funding source should be balanced to recognize that the Department of Labor & Industries is a payer and that <u>their financial support of the Turner cohort study leaves them with a vested interest equivalent to that of manufacturers that sponsor trials</u>. This language should be applied to the remaining funding discussions through the draft report.
    - The source of funding has long been a debate and consumers of healthcare information are not often informed. There is a strong collaboration between the manufacturer and the implanting physicians due to the manufacturer's need to understand the intricacies of product application in clinical and surgical settings during the product development process. Similarly, the physicians need to work closely with manufacturers in order to develop expertise in the technology and its application.
    - A 2005 JAMA article by Moses, et al. reported that *NIH provided 28% of biomedical research funding; 57% industry; remainder state, local, foundation, and other federal agencies. Cooperation between industry and academia is essential to bring new technologies to market in a timely manner for patients in need. Further, device trials sponsored by industry are regulated by FDA, whereas, government funded trials carried out at large academic centers are not. Risks can also go unreported in this setting*.
- **On page 77**, a comment is made that Medtronic collected and analyzed the data. While this is technically accurate, it is incomplete. The data were analyzed and interpreted by two separate statisticians, were 100% monitored, and a third independent statistical consultant had full access to the data. This adheres to the instructions for authors in JAMA which state *"For industry sponsored studies . . . an independent data analysis must be conducted by statisticians at an academic institution with access to the raw data set, rather than only by statisticians employed by the company sponsoring the research"* (JAMA. 2005;294:119-126). Further, but separate from the PROCESS trial, investigational device exemption (IDE) studies that are conducted by industry for premarket approval are subject to audit by the FDA. This type of rigor and scrutiny is not applied to research conducted by academia or state government.
- **On page 77**, regarding implanter experience, for completeness the authors need to raise the possibility that differences in outcome between RCTs and the Turner cohort study could reflect the lesser implanting experience of the implanters in the Turner study – to clarify this crucial point, the authors of the HTA report request details of the implanting experience of the included centers in the Turner cohort study and contrast this to the Kumar RCT centers.
- **On page 78**, a final sentence should be added to the section on pain relief efficacy stating that "Another RCT incorporated pain relief and patient satisfaction into a composite outcome "success", which was reported above." This insures that the data on pain relief from the North, et al. randomized

- **On page 77**, Key question #1, "Heterogeneity between studies...." – there is RCT evidence of the statistical and clinical superiority of SCS in both CRPS compared to medical management and for FBSS compared to both medical management and reoperation (see inappropriate aggregation of evidence discussed above).
- **On page 78,** Key question #3, Differential efficacy and effectiveness – we respectfully request this section be redrafted in the context on the comment of RCT based subgroup analysis discussed above.
- **On page 145,** the criteria for the 'overall strength of evidence' requiring 3 or more appropriately powered studies is unusual. Where does this criterion come from? Furthermore it is at odds with the expectancy of the FDA and EMEA for two confirmatory RCTs for licensing. Given there are two RCTs for FBSS both demonstrating superiority (statistical and clinical), FBSS should receive a 'high' strength of evidence rating. The rating of 'moderate' strength evidence for CRPS holds.
- **On page 147**, the quality assessment tool has been inappropriately applied by the authors – both Kemler and Kumar trials *did* conceal randomization and North trials had 98% follow up at 6-months and did not need to adjust for confounding as there was no evidence of differences in baseline characteristics. These three trials should therefore be reclassified as evidence class I.
- **On page 124**, Table 10 should be split into CRPS and FBSS. The quantity of evidence criteria of three or more trials seems inappropriate. Given that there are two positive trials of SCS for FBSS, there is strong evidence of efficacy AND effectiveness at < 3 years.
- **On page 147,** the Appendix E tables should be corrected based on the previous quality assessment of RCT commentary above.

Comments Pertaining to Key Question 2:

> ***2. What is the evidence of the safety of spinal cord stimulation? Including consideration of:***
> ***a. Adverse events type and frequency (mortality, major morbidity, other)***
> ***b. Revision and removal rates including loss of paresthesia (if not addressed in efficacy)***
> ***c. Infections***
> ***d. Lead migration***
> ***e. Technical malfunctions (e.g., early battery failure, broken leads)***

- **On page 16**, under Other SCS-related Side Effects, neurological defects should be changed to neurological **deficits**. Further, to state that a rate for these events could not be calculated, but that one RCT reported that every subject experienced an adverse event is misleading and suggests to the reader that the adverse event rate is 100%. This statement should be removed.
- **On page 82**, Table 6 is incorrectly labeled as containing data from RCTs when, in fact, the Turner cohort study is also included. This title should be corrected.
- **On page 16,** similar to the comments provides on key question #1 above, it is unreasonable that the summary conclusions on mortality suggest that the strength of evidence is high when mortality is not known to be an event attributable to SCS, that it is a rare event in clinical trials, and that only a limited number of studies are being used to inform the question. All known sources of experimental as well as longitudinal, observational data should be utilized regardless of length of follow-up. It is interesting to note that there appears to be only one other therapeutically-focused evidence report completed by Spectrum for WA State (hip resurfacing) that separates outcomes into short, mid, and long-term results. Further, in the hip resurfacing report, the following statement is included, which demonstrates that evidence requirements were not the same. That is, the evaluation methodology from one therapy to the next is not equivalent: "Short-term (< 5 years) safety data were reported by three national registry studies, two RCTs, and eight cohort studies (one prospective and seven

retrospective), while mid-term (5–10 years) safety data was reported by one retrospective cohort study, six case-series. No long-term safety data were available."

- **On page 16,** the manner in which the conclusions are presented also leaves the reader questioning whether mortality is a concern. That is, the Strength of Evidence "High" can be misinterpreted as "High risk of mortality". We respectfully request the addition of an asterisk to this portion of the summary conclusions that remind the reader that Strength of Evidence "High" does not equate to a high risk of mortality.
- **On page 16**, the summary section on mortality should include the statement that is listed on page 92: "In no case was the cause of death attributed to the SCS device or procedure for implanting or revising the device." In this section, it is inappropriate to include a comment about a life-threatening complication that arose from trial stimulation. This complication would be included in the Other SCS-related Side Effects and is a risk inherent in any surgical procedure and is not specific to SCS. In the interim report released by Washington State, the near death complication was attributed to operator error.
- **On page 16**, the summary section on mortality states that no deaths occurred in the comparator groups yet provided the data point 1/149 suggesting that a death, in fact, occurred. This inconsistency should be resolved.
- What is clearly missing from the section on mortality is a robust discussion about the mortality risk associated with other surgical procedures as well as non-operative treatments - - necessary context to ensure informed consideration. Statistics about mortality associated with oral opioid use and spine surgery are presented. **See Appendix #6.**
- **On page 92**, the reference to and discussion of the Coffey, et al. article should be removed. Spectrum notes that the study did not meet their inclusion criteria, however, they proceed to introduce data from the study. If this information is retained in the final report, it must be clarified that the mortality is **all-cause** mortality.
- With respect to revision, the SCS technology used in the RCTs included older non-rechargeable generators and mostly quadripolar lead(s). Today, rechargeable generators with a longer, 9-year battery life (Medtronic) and dual octapolar leads are commonly used. Both of these advancements may allow for fewer surgical revisions.
    - A generator replacement due to normal battery depletion should not be considered an adverse event. **On page 86**, the generator replacement due to end of battery life should be removed from the list as a complication.
- With respect to the revision rate and other SCS-related adverse events, other observational data sources and systematic reviews of the literature provide a more complete picture and should be taken into consideration. Additional data are provided. **See Appendix #7.**
- **On page 125**, Table 11 regarding the assessment of quantity of evidence is inconsistent with Table 10. There is evidence of variation of the frequency of complications of SCS across studies that likely reflects the varying experience of the implanting center. Therefore, consistency is low and strength of evidence should be downgraded accordingly. Finally, this table and the section on safety fails to contextualize the nature of the SCS-related complications i.e. relatively minor and reversible.

In addition to safety information available in the published clinical literature, Medtronic uses a prospective, long-term multi-center registry study, titled the Implantable Systems Performance Registry (ISPR) to monitor the performance of certain products at selected centers throughout the United States. The full 2009 Product Performance Report can be viewed online at http://professional.medtronic.com/performance09/spinal-cord-stimulation-systems/index.htm.

Safety of Spinal Cord Stimulation: ISPR

Registry data were collected between June 2004 and the report cut-off date of October 24, 2008. Forty-two centers enrolled and contributed patients to the spinal cord stimulation section of the report. Of the 1,373 total spinal cord stimulation patients enrolled in the ISPR, 46.7% were implanted with a spinal cord stimulation system for the treatment of failed back, 40.6% for treatment of other indications, and 12.7% for treatment of complex regional pain syndrome (CRPS).

Product Performance-Related Events

There were 652 events reported between June 2004 and October 24, 2008 in 1,373 patients with spinal cord stimulation systems. Twenty-seven percent of these events (173/652) were related to the spinal cord stimulator, lead, or extension, and categorized as product performance related events and are shown in **Appendix #8.**

Non-Product Performance-Related Events

Twenty-eight percent of total events (184/652) were related to the surgery or procedure (n=75), or attributed to the patient or delivery of the therapy (n=109). Twenty-four percent of events (155/652) were due to the patient expiring or becoming lost to follow-up (e.g., patient moved, transferred care to another provider, study withdrawal). No deaths were reported as a result of a device related event or the delivery of neurostimulation therapy. Twenty-one percent of events (140/652) were related to normal battery depletion. Details are provided in **Appendix #9.**

Comments Pertaining to Key Question 3:

3. What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender
b. Age
c. Psychological or psychosocial co-morbidities
d. Diagnosis or pain type
e. Other patient characteristics or evidence based patient selection criteria
f. Provider type, setting or other provider characteristics (e.g. Health care system type, including worker's compensation, Medicaid, state employees)

The differential efficacy and effectiveness of technologies should be addressed by pre-defined subgroup (interaction) analyses undertaken within RCTs. In the hierarchy of evidence, trial based subgroup analyses outweigh the findings of observational (prognostic) studies as undertaken by the authors of this report. This report does not systematically review the RCT subgroup evidence (e.g. Kumar RCT included predefined subgroups). Using trial based subgroup evidence, the more appropriate interpretation is that there is currently no evidence to support the differential efficacy and effectiveness in SCS in particular patient subgroups or therapy settings. If other analyses of prognostic factors are to be considered, there were some that were excluded from the analysis due to being LoE III or were missing:

- The North 2005 RCT reported that "*Analysis of prognostic factors by multivariate logistic regression revealed that patients randomized to reoperation (P=0.02) and patients who were using narcotic analgesics before surgery (P =0.02) were significantly more likely to "fail" their randomized treatment by this outcome measure, that is, they were significantly more likely to cross over to the alternative treatment.*"
- The Kumar 22-year experience paper from Neurosurgery 2006 contains a section devoted to clinical prognostic factors including analysis of *etiology of pain, age, sex, laterality of pain, preimplant surgeries, duration of pain prior to implantation, and effect of rapid cycling*. Given the large sample size (n=410) and average length of follow-up (8.1 years), this is one of the most important longitudinal, observational studies of SCS that allows for exploration of factors that may assist in patient selection.
- Research presented at the 2009 North American Neuromodulation Society found a significant association between time to SCS implant and outcomes. A summary of these data by Kumar and colleagues is shown in **Appendix #10**.

- **On page 95**, under the Workers' Compensation (WC) section, the Burchiel 1995 study is cited as the one study that found no difference between WC or other third party coverage compared to those patients not under such programs with respect to the percentage of patients that achieved ≥50% pain relief. It seems inaccurate not to include the Turner 2010 cohort study in this section. Further, the North 2005 did not find that WC patients were more likely to fail treatment.

Comments Pertaining to Key Question 4:

4. What evidence of cost implications and cost-effectiveness of spinal cord stimulators? Including consideration of:

a. Costs (direct and indirect) in short term and over expected duration of use

b. Replacement

- **On page 109**, Spectrum notes that "Differences in health care systems and reimbursement in the UK make transferring results from their economic evaluations [difficult?]." Data recently presented at the 2010 Health Technology Assessment International (HTAi) conference is worth noting due to its ability to directly address this concern. These data adapt the UK cost effectiveness model used in the NICE evaluation to the U.S. healthcare system. Data are presented in **Appendix #11**.
- **On page 109**, paragraph 1, SCS+CMM was not shown to be dominant over CMM alone but rather more cost effective. Given the authors' expressed concern about industry bias, the independent nature of the NICE commissioned HTA and review of the evidence for SCS could be mentioned.

IV. Conclusion

Thank you in advance for your thoughtful consideration of this information. We believe that this information will help to provide a more balanced, comprehensive summary of the current evidence for spinal cord stimulation. Regardless of the methodology used to review the clinical evidence and the guidelines and recommendations put forth at a national, society, or individual private payer level, there is simply no other conclusion one can make other than coverage of spinal cord stimulation for appropriately selected patients.

- Empirical clinical and cost-effectiveness literature available, which while not perfect, overall supports appropriate use of this therapy for patients in chronic pain who have failed more conservative treatment options;
- The governing related Medicare National Coverage Decision supports coverage for this therapy;
- The consensus of national expert medical society guidelines and opinions broadly support appropriate coverage for this therapy;
- Treatment guidelines and policies including state-based and private payers broadly support appropriate coverage for this therapy;
- While not included here, perhaps the most compelling data are the stories of Washington residents whose lives have been significantly helped by spinal cord stimulation.

We stand ready to assist the Washington Health Care Authority and the Health Technology Clinical Committee in their review and delineation of a coverage policy that, hopefully, both serves to protect patients as well as ensure that, when appropriate, they have access to this life-changing, cost-effective implantable therapy. Should you have any questions please do not hesitate to contact William Fehrenbach at 763-607-1378 or at william.fehrenbach@medtronic.com as he can best coordinate internal expertise and a timely response and best ensure your needs are met.

Sincerely,

N. William Fehrenbach
Reimbursement Director
State Government Affairs
Evidence Based Medicine and
Coverage & Authorization Services

7000 Central Avenue NE, RCE395
Minneapolis, MN 55432
Office: 763-526-8193
Cell: 763-607-1378
william.fehrenbach@medtronic.com

Jennifer Hinnenthal
Sr. Manager
Evidence Based Medicine

7000 Central Ave NE, RCE395
Minneapolis, MN 55432
Office: 763-526-6068
jennifer.hinnenthal@medtronic.com

Appendix #1: SCS for Back/Leg Pain Guidelines in National Guideline Clearinghouse

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]. 2008 Oct. 33 pages. NGC:006752 http://www.guideline.gov/summary/summary.aspx?doc_id=13305&nbr=006752&string=%22spinal+cord+stimulat*%22	FBSS and CRPS; Evidence considered for these indications separately. [Remainder of indications redacted]	1 Guidance. 1.1 Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who: continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of the assessment specified in recommendation 1.3. 1.2 [Redacted] 1.3 Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed. 1.4 When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with spinal cord stimulation. Tests to assess pain and response to spinal cord stimulation should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted. 1.5 If different spinal cord stimulation systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered.	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
		1.6 [Redacted]	
EFNS guidelines on neurostimulation therapy for neuropathic pain. European Federation of Neurological Societies - Medical Specialty Society. 2007 Sep. 19 pages. NGC:005909 http://www.guideline.gov/summary/summary.aspx?doc_id=11372&nbr=005909&string=%22spinal+cord+stimulat*%22	FBSS and CRPS; Evidence considered for these indications separately. [Remainder of indications redacted]	Recommendations: We found level B evidence for the effectiveness of SCS in FBSS and CRPS I. The available evidence is also positive for CRPS II, …[redacted], but still requires confirmatory comparative trials before the use of SCS can be unreservedly recommended in these conditions.	**POSITIVE**
Assessment and management of chronic pain. Institute for Clinical Systems Improvement - Private Nonprofit Organization. 2005 Nov (revised 2008 Jul). 84 pages. NGC:006693 http://www.guideline.gov/summary/summary.aspx?doc_id=12998&nbr=006693&string=%22spinal+cord+stimulat*%22	FBSS and CRPS; [Remainder of indications redacted]	Spinal Cord Stimulation (SCS): Patients with lumbar and cervical radiculopathy who are not surgical candidates, patients with postlaminectomy syndrome, and patients with complex regional pain syndrome (CRPS) type 1 or (RSD) are the best candidates for SCS.….[redacted] Level 1 Management of Mechanical/Compressive Pain: Invasive treatments have limited scientific evidence supporting their use. These include:...spinal cord stimulation... Level II Management: Interdisciplinary Team Referral, Plus a Pain Medicine Specialty Clinic, Surgical Management of Chronic Pain : Neurosurgical techniques for chronic pain that is resistant to a conservative approach hold promise, but have limited scientific evidence. These include:...spinal cord	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
*Pending Update. The most current version dated Nov 2009 contains same language shown at right and can be viewed at: http://www.icsi.org/pain__chronic__assessment_and_management_of_14399/pain__chronic__assessment_and_management_of__guideline_.html		stimulation...	
American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, et al. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician 2009 Jul-Aug;12(4):699-802. NGC:007428. http://www.guideline.gov/summary/summary.aspx?doc_id=12998&nbr=006693&string=%22spinal+cord+stimulat*%22	FBSS	***6.7.4 Indications*** While multiple indications are available, the indications in the United States are related to neuropathic pain of FBSS or CRPS. ***6.7.5 Level of Evidence*** The indicated evidence for SCS is Level II-1 or II-2 for long-term relief in managing patients with FBSS. ***6.7.6 Recommendations*** Based on Guyatt et al's (136) criteria, the recommendation is 1B or 1C/strong recommendation for clinical use on a long-term basis.	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
Low back disorders. American College of Occupational and Environmental Medicine - Medical Specialty Society. 1997 (revised 2007). 366 pages. NGC:006456 http://www.guideline.gov/summary/summary.aspx?doc_id=12540&nbr=006456&string=%22spinal+cord+stimulat*%22 *See Appendix B for detailed discussion of the controversies surrounding ACOEM*	Radicular pain syndrome, FBSS, LBP; Evidence considered for these indications separately	Spinal cord stimulators are not recommended for treatment of acute, subacute, or chronic LBP. They also are not recommended for treatment of radicular pain syndromes or failed back surgery syndrome.* Not Recommended, Insufficient Evidence (I) * Spinal cord stimulators may be considered as a late or last resort for highly selected patients who have failed multiple other conservative treatments including a quality functional restoration program and who have had a forensic psychologic assessment (83 percent Panel agreement).	**POSITIVE*** *Even this guideline, considered very conservative by many, envisions appropriate use of SCS for FBSS and CRPS for certain candidates.
Pain (chronic). Work Loss Data Institute - Public For Profit Organization. 2003 (revised 2008 May 19). 475 pages. NGC:006564 http://www.guideline.gov/summary/summary.aspx?doc_id=12676&nbr=006564&string=%22spinal+cord+stimulat*%22	FBSS and CRPS; Evidence considered for these indications separately [Rest of indications redacted]	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. [Remainder of the background data on history, safety and efficacy of therapy not shown here] Indications for stimulator implantation: Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: (1) symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.); (2) psychological clearance indicates realistic expectations and clearance for the procedure; (3) there is no	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
		current evidence of substance abuse issues; (4) there are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence. Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)…[Redacted]	
Evidence-based clinical practice guidelines for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients. Siskin Hospital for Physical Rehabilitation (Chattanooga, TN) - Hospital/Medical Center. 1995 (revised 2005). 41 pages. NGC:004500 http://www.guideline.gov/summary/summary.aspx?doc_id=8014&nbr=004500&string=%22spinal+cord+stimulat*%22	Chronic nonmalignant pain syndrome	Implantable Infusion Pumps and Spine Stimulation Devices. Studies and systematic reviews regarding the efficacy of infusion pumps and spinal cord stimulators have increased. Thus far, they have not met the current criteria for adequate supportive evidence to recommend application to CPS* patients....Given the continued absence of quality research showing consistent and clinically significant evidence, the current guidelines do not recommend using implantable infusion pumps or spinal cord stimulators with CPS patients. *CPS is defined as: any set of behaviors that: 1. involves the complaint of enduring or recurring pain; 2. has persisted longer than typical for an associated condition, or is associated with an intermittent or chronic disease process; 3. has responded inadequately to appropriate medical and/or invasive care; and 4. is associated with significant and reliable impairment of functional status. Chronic nonmalignant	**NEGATIVE*** *Interestingly, this guideline speaks only to CPS and not to FBSS or CRPS which are the commonly listed indications for SCS.

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
		pain syndrome patients may also demonstrate significant mood disturbance and/or anger—hostility, but these are not considered as necessary to make a diagnosis.	
Low back - lumbar & thoracic (acute & chronic). Work Loss Data Institute - Public For Profit Organization. 2003 (revised 2008 Jun 10). 481 pages. NGC:006562 http://www.guideline.gov/summary/summary.aspx?doc_id=12674&nbr=006562&string=%22spinal+cord+stimulat*%22	FBSS and CRPS; Evidence considered for these indications separately [Rest of indications redacted]	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for Indications for stimulator implantation.	**POSITIVE**
Complex regional pain syndrome: treatment guidelines (third edition). Reflex Sympathetic Dystrophy Syndrome Association - Private Nonprofit Organization. 2002 Feb (revised 2006 Jun). 67 pages. NGC:005233 http://www.guideline.gov/summary/summary.aspx?doc_id=9768&nbr=005233&string=%22spinal+cord+stimulat*%22	CRPS	Interventional Therapies: Our recommended strategy (and tactic) is to use interventional treatments for CRPS patients who are having difficulty either starting or progressing in the functional restoration/interdisciplinary algorithm. If patients are not progressing because of high pain levels (especially associated with autonomic dysfunction), then a stepwise progression — from the less invasive blocks, to infusions or catheter infusion therapies, and ultimately perhaps to neurostimulation — is recommended in order to facilitate the patient's functional improvement and pain control. One suggested algorithm developed by an expert panel for the integrated use of these procedures is shown below and has been previously published. Interventional Pain Treatment Algorithm for CRPS (from Stanton-Hicks 2002)	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
		Step 1 Minimally Invasive Therapies Sympathetic Nerve Blocks Intravenous Regional Nerve Blocks Somatic Nerve Blocks Step 2 More Invasive Therapies Epidural and Plexus Catheter Block(s) Neurostimulation Intrathecal Drug Infusion (e.g., Baclofen) Step 3 Surgical and Experimental Therapies Sympathectomy Motor Cortex Stimulation Inadequate or partial response to any given therapy should lead to a stepwise progression down through these modalities (moving from less to more invasive) in conjunction with other noninterventional treatments.	
Diagnosis and treatment of degenerative lumbar spinal stenosis. North American Spine Society - Medical Specialty Society. 2002 (revised 2007 Jan). 262 pages. NGC:005896 http://www.guideline.gov/summary/summary.aspx?doc_id=11306&nbr=005896&string=%22spinal+cord+stimulat*%22	Spinal stenosis	A systematic review of the literature yielded insufficient evidence to address the role of traction, electrical stimulation or TENS in the treatment of lumbar spinal stenosis. Grade of Recommendation: I (Insufficient Evidence) An extensive review of all articles cited in the reference section found no direct comparison of ancillary treatments (traction, electrical stimulation or TENS) to an untreated control group (natural history)	**N/A** Note: This guideline is specific to stenosis only. Electrical stimulation named, but not spinal cord stimulation specifically.

Appendix #2: Three additional SCS guidelines from specialty societies

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
ACOEM Chronic Pain Chapter *ACOEM guidelines are for purchase only. There is no link we can provide that grants access. The general link to the ACOEM guidelines website is:* http://www.acoem.org/practiceguidelines.aspx	CRPS	**Implantable Spinal Cord Stimulators for Complex Regional Pain Syndrome (CRPS) [Chronic] - Recommended - Limited Evidence (C).** SCS implantation is recommended as an option for highly select CRPS patients who understand that this intervention has no demonstrated long-term benefits and is for short- to intermediate-durations during which time there is unequivocal patient commitment and adherence to a functional restoration program. **Implantable Spinal Cord Stimulators for Complex Regional Pain Syndrome (CRPS) [Chronic] - Not Recommended - Insufficient Evidence (I).** SCS implantation is not recommended for long-term relief (>3 years) of CRPS as there is no evidence that long-term benefits from SCSs are superior to those obtained from quality functional restoration programs.	**POSITIVE*** *Interestingly, this conservative guideline also believes SCS is supported in some circumstances.
American Pain Society APS Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain. An Evidence-Based Clinical Practice		Nonradicular Low Back Pain: No trials exist for nonspecific low back pain so authors were unable to estimate net benefit. Grade I.[2] Radiculopathy or Spinal Stenosis: No trials for radiculopathy with prolapsed lumbar disc exist so authors were unable to estimate net benefit. Grade I. For failed back surgery syndrome with persistent radiculopathy, the level of evidence is	**POSITIVE**

[2] APS Definitions: Grade I = The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. Fair = Evidence is sufficient to determine effects on health outcomes, but the strength of evidence is limited by the number, quality, size or consistency of included studies; generalizability to routine practice; or indirect nature of evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher quality trials with some inconsistency, at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodological flaws). Moderate = Pain scale improvement is mean 10-20-point improvement on a 100-point VAS or equivalent. Back-specific functional status is a mean 10-20-point improvement on the ODI, 2-5 points on the RDQ, or equivalent. All outcomes: standardized mean difference, 0.5-0.8. Grade B = The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention. Weak = Benefits and risks and burdens are finely balanced.

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
Guideline from the American Pain Society (Chou R, et al. *Spine* 2009;34(10):1066-77)		Fair with a Moderate net benefit. Grade B. Language included in their recommendation is as follows: "In patients with persistent and disabling radicular pain following surgery for herniated disc and no evidence of a persistently compressed nerve root, it is recommended that clinicians discuss risks and benefits of spinal cord stimulation as an option (weak recommendation , moderate-quality evidence). It is recommended that shared decision-making regarding spinal cord stimulation include a discussion about the high rate of complications following spinal cord stimulator placement."	*Supports use for treatment of radicular pain following surgery.*
American Society of Anesthesiologists ASA Practice Guidelines for Chronic Pain Management Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. American Society of Anesthesiologists Task Force on Chronic Pain		Electrical Nerve Stimulation, Spinal cord stimulation: Spinal cord stimulation may be used in the multimodal treatment of persistent radicular pain in patients who have not responded to other therapies. It may also be considered for other selected patients (e.g., complex regional pain syndrome, … [redacted]). Shared decision-making regarding spinal cord stimulation should include a specific discussion of potential complications associated with spinal cord stimulator placement. A spinal cord stimulation trial should be performed before considering permanent implantation. of a stimulation device. Recommendations for Electrical Nerve Stimulation, Spinal cord stimulation: One randomized controlled trial reports effective pain relief for complex regional pain syndrome patients at follow-up assessment periods of 6 months-2 years when spinal cord stimulation in combination with physical therapy is compared to physical therapy alone. [Category A3 evidence] One randomized controlled trial reports effective pain relief for an assessment period of 6 months when failed lumbosacral spine surgery patients are treated with spinal cord stimulation compared to reoperation. [Category A3 evidence]	**POSITIVE**

Guideline and Society/Organization	Indication(s)	Excerpted Language on SCS	Recommendation
Management; American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. 2010 Apr;112(4):810-33.		Studies with observational findings report that spinal cord stimulation also provides pain relief for other conditions (e.g., [redacted]). [Category B2 evidence] Reported side effects include insertion-site pain and infections. [Category B2 evidence] The ASA members agree, and the consultants and ASRA members strongly agree that spinal cord stimulation should be used for persistent radicular pain; and they all agree that it should be used for other conditions (e.g., [redacted]… complex regional pain syndrome, … [redacted]). The consultants, ASA members, and ASRA members strongly agree that a spinal cord stimulation trial should be performed before considering permanent implantation of a stimulation device.	

Appendix #3: NICE Technology Assessment Guidance

Health Technology Assessment	Language	Guidance
Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]. 2008 Oct. 33 pages. NGC:006752 The full technology assessment report can be viewed at: http://www.nice.org.uk/nicemedia/live/12082/42367/42367.pdf	1 Guidance. 1.1 Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who: continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of the assessment specified in recommendation 1.3. 1.2 [Redacted] 1.3 Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed. 1.4 When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with spinal cord stimulation. Tests to assess pain and response to spinal cord stimulation should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted. 1.5 If different spinal cord stimulation systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered. 1.6 [Redacted]	**POSITIVE**

Appendix #4: Economic Endpoints from Simpson, et al. Systematic Review, Table 35

FBSS: SCS+CMM vs. CMM	SCS+CMM	CMM	Difference
Total discounted costs	£88,443	£78,408	£10,035
Discounted QALYs	5.30	4.05	1.26
ICER			£7,996
FBSS: SCS+CMM vs. reoperation	SCS+CMM	Reoperation	Difference
Total discounted costs	£87,674	£78,244	£9,430
Discounted QALYs	6.94	5.60	1.34
ICER			£7,043
CRPS: SCS+CMM vs. CMM	SCS+CMM	CMM	Difference
Total discounted costs	£86,280	£77,505	£8775
Discounted QALYs	7.71	7.36	0.35
ICER			£25,095

Appendix #5: SCS Private Payer Coverage Policies for WA State Residents and Top 10 National Private Payers

WA State Payer and Covered Lives	SCS Language	Coverage
AETNA Health Inc. - 309,017 covered lives 151 Farmington Avenue, Hartford, CT 06156 www.aetna.com Contracted or Affiliated PBM(s): Aetna Pharmacy Management (APM) States Served: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KA, KY, LA, ME, MD, MA. MI, MN, MS, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY http://www.aetna.com/cpb/medical/data/100_199/0194.html	**Excerpt-** Aetna considers dorsal column stimulators (DCS) medically necessary durable medical equipment (DME) for the management of members with chronic pain due to: (i) failed back surgery syndrome with low back pain and significant radicular pain, (ii) complex regional pain syndrome (also known as reflex sympathetic dystrophy), or (iii) [redacted]: -There is documented pathology, i.e., an objective basis for the pain complaint, and -Other more conservative methods of pain management have been tried and failed, and -Member does not have any untreated existing drug addiction problems (per American Society of Addiction Medicine (ASAM) guidelines), and -Member has obtained psychiatric clearance, and -Member has predominantly radiating extremity pain, and -Member experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief.)	**POSITIVE**
Asuris Northwest Health – 57,242 covered lives 528 East Spokane Falls Boulevard, Suite 301, Spokane, WA 99202 www.asuris.com Contracted or Affiliated PBM(s): RegenceRx States Served: 14 counties in Eastern Washington. Telephone (Automated): (888) 344-5593 Regence BlueShield. Not-Ownership: for-profit. Private. http://blue.regence.com/trgmedpol/surgery/sur45.html	**Excerpt-** I. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations apply: A. Spinal cord stimulation may be considered medically necessary for the treatment of either of the following conditions and when all patient selection criteria in B. below have been met: 1. Severe and chronic pain of the trunk or limbs other than critical limb ischemia that is refractory to all other pain therapies, or 2. [redacted]. B. All of the following Patient Selection Criteria must be met: 1. The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated. 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, [redacted]. 3. No serious untreated drug habituation exists. 4. Patient was carefully screened, evaluated and diagnosed by a multidisciplinary pain management team prior to application of these therapies. 5. Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation. II. Spinal cord stimulation is considered investigational for all other indications including but not limited to treatment of the following: [redacted]	**POSITIVE**

Blue Cross & Blue Shield of Rhode Island - 387 444 Westminster Street, Providence, RI 02903 www.bcbsri.com Contracted or Affiliated PBM(s): WellPoint NextRx States Served: Rhode Island. Alias(es): Coordinated Health Partners is the HMO subsidiary of Blue Cross and Blue Shield of Rhode Island. Ownership: Not-for-profit. Private. https://www.bcbsri.com/BCBSRIWeb/plansandservices/services/medical_policies/SpinalCordStimulation.jsp	**Excerpt-** Spinal cord stimulation is used to interfere with the transmission of pain signals to the brain and to provide relief from chronic pain. The sensation of pain is blocked by applying low-voltage electrical impulses to stimulate targeted nerves along the spinal cord. The repetitive electrical impulses are delivered to the spinal cord using an electronic device connected to a strip of electrodes surgically implanted in the epidural space. A magnetic remote control is used to turn the current on/off and to adjust the current for optimal pain relief. Treatment is a two-step process. Initially a trial procedure is performed to assess effectiveness in the specific patient. This surgical procedure is typically performed in an outpatient hospital or day-surgery center. Length of the trial period depends on severity of pain and physician determination, but most trials range from a few days to several weeks. A good outcome after a trial procedure is defined as pain relief of 50 per cent or better. If the initial procedure is successful, a permanent stimulator is implanted. Guidelines for the use of spinal cord stimulation: -Treatment is used only as a last resort after other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and have failed, or, are judged to be unsuitable or contraindicated; -Pain is neuropathic in nature; i.e., resulting from damage to the peripheral nerves; -No untreated drug addictions; -Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation, and -Initial trial resulted in at least 50 per cent improvement in pain relief. Spinal cord stimulation for the treatment of critical limb ischemia as a technique to forestall amputation is not covered due to insufficient evident demonstrating clinical efficacy. Spinal cord stimulators (generator or receiver) are typically replaced every two to three years.	**POSITIVE**
Blue Cross and Blue Shield of Nebraska - 8,647 7261 Mercy Road, Omaha, NE 68180 www.bcbsne.com Contracted or Affiliated PBM(s): Prime Therapeutics, Inc. States Served: Nebraska. Telephone (Automated): (800) 642-8980 Mutual insurance Ownership: company. Private. https://www.bcbsne.com/PDFs/Provider/Library/Manuals/Medical_Policy_Manual.pdf Keyword Search "SPINAL CORD AND DEEP BRAIN STIMULATION"	**Excerpt-** The use of spinal cord and deep brain stimulation is to be utilized as follows: -The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated; -Demonstration of pain relief with a temporary implanted electrode precedes permanent implantation; -Patients are carefully screened, evaluated, and diagnosed by a multidisciplinary team prior to application of these therapies; and -All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available. Implantation of the spinal cord stimulator is typically a two-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed, the electrodes and radio-receiver/transducer are permanently implanted.	**POSITIVE**

BlueCross BlueShield of Tennessee – 4,818 801 Pine Street, Chattanooga, TN 37402 www.bcbst.com Contracted or Affiliated PBM(s): Caremark Rx, Inc. States Served: Tennessee. Telephone (Automated): (800) 565-9140 Alias(es): Volunteer State Health Plan, TennCare Select Ownership: BlueCross BlueShield of Tennessee, Inc. Not-for-profit. Private. http://www.bcbst.com/mpmanual/Spinal_Cord_Stimulation_for_Treatment_of_Pain.htm	**Excerpt-** A trial spinal cord stimulation associated with the following conditions/diseases is considered medically necessary if the medical appropriateness criteria are met: -Radiculopathies (diseases or conditions involving the nerve roots, including failed back surgery syndrome [FBSS], arachnoiditis and epidural fibrosis) -Reflex sympathetic dystrophy (also known as complex regional pain syndrome type 1 -Intractable pain from severe peripheral vascular disease. Permanent implantation is considered medically necessary if the medical appropriateness criteria are met. Medical Appropriateness Criteria: Trial SCS is considered appropriate if ALL of the following criteria are met: -SCS is a late or last resort for an individual with chronic intractable pain -Other treatment modalities (e.g., pharmacologic, surgical, physical, or psychologic therapies) have been tried for at least 6 months and failed, or were judged unsuitable, or contraindicated -Careful screening, evaluation, and diagnosis by a multi-disciplinary team are undertaken prior to the implantation. Such screening must include psychological as well as physical evaluation. Permanent implantation is considered medically appropriate if there is a demonstration of pain relief for 5 to 10 days with a temporarily implanted electrode.	**POSITIVE**
Bluegrass Family Health, Inc. – 1 651 Perimeter Drive, Suite 300, Lexington, KY 40517 www.bgfh.com Contracted or Affiliated PBM(s): Caremark Rx, Inc. States Served: Kentucky. Ownership: Baptist Healthcare System, Inc. (Louisville, KY). Not-for-profit. Private. Chief Executive Officer: James S. Fritz http://www.bgfh.com/snm_asp_3524_providers.asp Select "Coverage Issues", Keyword search: Pain Management	Spinal Cord Stimulation is considered medically necessary with established trial and failure of conservative therapies, who have undergone evaluation by a psychiatrist or a behavioral medicine professional specializing in pain, which has identified the member as an appropriate candidate for SCS trial, and then have undergone a trial of SCS stimulation with a reduction of >50% of pain. Patients shall have undergone careful screening and diagnosis by a multidisciplinary team before implantation, have no documented or described drug/substance abuse/addiction issues, and have demonstrated pathology as an objective source of the pain. Recognized conditions for which this modality is appropriate include: pain of neurogenic origin, extremity pain secondary to peripheral vascular disease, and pain secondary to severe disabling RSD/RCPD that has been unresponsive to conventional therapy for a minimum of six month duration.	**POSITIVE**
CIGNA HealthCare, Inc. - 130,080 covered lives 900 Cottage Grove Road, Bloomfield, CT 06002 www.cigna.com Contracted or Affiliated	**Excerpt –** CIGNA covers a short-term trial of spinal cord stimulation (SCS) for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when BOTH of the following criteria are met: • There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management. • Appropriate mental health screening has	**POSITIVE**

PBM(s): CIGNA Pharmacy Management States Served: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KA, KY, LA, ME, MD, MA. MI, MN, MS, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY Alias(es): Connecticut General Life Insurance Company, Great-West Healthcare Ownership: CIGNA HealthCare, Inc. For-profit. Public. NYSE: CI http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0380_coveragepositioncriteria_spinal_cord_stimulation.pdf	been completed, and there is no evidence of an inadequately controlled mental heath problem. CIGNA covers permanent implantation of a spinal cord stimulator for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when ALL of the following criteria are met: • There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management. • Appropriate mental health screening has been completed, and there is no evidence of an inadequately controlled mental heath problem. • Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation. CIGNA covers a short-term trial of spinal cord stimulation (SCS) for the treatment of pain secondary to [redacted]. CIGNA covers permanent implantation of a spinal cord stimulator for the treatment of pain secondary to [redacted].	
Group Health Cooperative - 509,208 covered lives 320 Westlake Avenue North, Seattle, WA 98109 www.ghc.org Ownership: Group Health Cooperative. Not-for-profit. Private. Contracted or Affiliated PBM(s): MedImpact Healthcare Systems, Inc. States Served: Idaho, Washington. Alias(es): Group Health Options https://provider.ghc.org/all-sites/clinical/criteria/pdf/spinal_cord_stimulator_for_pain.pdf	**Excerpt –** Dorsal column (spinal cord) neurostimulation -The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space. These implants are covered when all of the conditions listed below have been met: - Documentation supports that the implantation is a late resort (if not a last resort) in the treatment of chronic intractable pain: - other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient - Documentation shows evidence of careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation); -Documentation that demonstrates pain relief from a temporarily implanted electrode prior to permanent implantation.	**POSITIVE**
Group Health Incorporated (GHI) - 802 441 Ninth Avenue, New York, NY 10001 www.ghi.com, www.emblemhealth.com	**Excerpt-** Members are eligible for coverage of DCS implantation as an in-patient procedure for the following indications (A, B or C): A. Nonmalignant pain: DCS is covered for managing chronic, intractable, nonmalignant pain in patients who meet all of the following criteria: -Conservative methods of pain management have	**POSITIVE**

Contracted or Affiliated PBM(s): Express Scripts, Inc. States Served: New York and Nationwide. Telephone (Automated): (212) 501-4444 Alias(es): GHI HMO and GHI Select Ownership: EmblemHealth, Inc. Not-for-profit. Private. http://www.emblemhealth.com/pdf/med_guidelines/surgical/MG_Dorsal_Column_Stimulator_aC.pdf	been tried and failed. -Contraindication for further surgical intervention. -Absence of any untreated existing drug addiction problems. -Psychiatric clearance obtained (documented member assessment of emotional stability must be completed by a provider other than the surgeon, e.g., psychiatrist or psychologist). -Pain is predominantly neuropathic. -Pain reduction achieved with a 3- to 7-day trial of percutaneous spinal stimulation. OR DCS may be covered for chronic non-malignant pain patients who do not meet the above listed criteria if the psychiatrist or psychologist determines that the patient is suicidal. B. Angina: DCS is covered for the management of intractable angina in patients who are not surgical candidates and whose pain is unresponsive to all standard therapies when all of the following criteria are met: -Angiographically documented significant coronary artery disease and contraindication for revascularization procedures such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty. -Angina pectoris is New York Heart Association Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms increase with physical activity). -Reversible ischemia documented by symptom-limited treadmill exercise test. -Optimal pharmacotherapy tried for at least one month. Optimal pharmacotherapy includes the maximum tolerated dosages of at least two of the following antianginal medications: long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists. -Significant pain reduction (50% or more) achieved with a 3- to 7-day trial of percutaneous spinal stimulation. C. Refractory neuropathic pain including peripheral polyneuropathy of the extremities from multiple etiologies including diabetes, toxic-metabolic, ischemic or neoplastic deafferentation syndrome (i.e. traumatic including nerve root avulsion injury), autoimmune [multiple sclerosis, Guillain Barre or chronic demyelinating polyneuropathy) or infectious (herpes zoster), spinal cord injury or cauda equina injury, chronic pain due to traumatic injuries.	
Health Net Health Plan of Oregon, Inc. - 18,000 covered lives 13221 SW 68th Parkway, Suite 200, Tigard, OR 97223 www.healthnet.com Contracted or Affiliated PBM(s): Health Net Pharmaceutical Services; Caremark Rx, Inc. States Served: Oregon, Washington. Health Net, Inc. For-profit. Private subsidiary of Ownership: public company.	**Excerpt-** Health Net, Inc. considers dorsal column stimulation (DCS) medically necessary when all of the following are met: -The implantation of the stimulator is used only as a last resort for patients with chronic intractable pain; -Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient; -Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation); -All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient must be available; and -Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation. -Patients with chronic intractable pain due to any of	**POSITIVE**

NYSE: HNT https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/dorsal_column_stimulators_apr_08.pdf	the following: -Lumbosacral adhesive arachnoiditis secondary to multiple myelographies or lumbar surgeries that has not responded to medical management, including physical therapy (the presence of arachnoiditis is usually documented by the presence of high levels of proteins in the CSF and/or by myelography or MRI.); -Nerve root injuries, post surgical or post traumatic (e.g., avulsion), including that of post-laminectomy syndrome (failed back syndrome); -Complex regional pain syndrome I & II (term causalgia reflex sympathetic dystrophy changed to complex regional pain syndrome I & II); -[redacted].	
Humana, Inc. - 79,700 500 West Main Street, Louisville, KY 40202 www.humana.com Contracted or Affiliated PBM(s): Argus Health Systems, Inc. (retail), RightSource (mail order-in-house) States Served: Nationwide. Alias(es): This record incorporates CarePlus, CHA Health, MetCare Health Plans (aka AdvantageCare), and OSF Health Plans acquisitions, formerly listed separately, as well as KMG America acquisition. Ownership: Humana, Inc. For-profit. Public. NYSE: HUM http://apps.humana.com/tad/tad_new/Home.aspx	**Excerpt-** Humana members MAY be eligible under the Plan for spinal cord stimulation for the following conditions: • Diabetic neuropathy; OR • Failed back surgery syndrome (FBSS) with primarily radicular pain; OR • Inoperable chronic critical limb ischemia; OR • Reflex sympathetic dystrophy (RSD)/complex regional pain syndrome (CRPS). Temporary Trial A temporary trial of spinal cord stimulation MAY be covered for any of the conditions listed above when ALL of the following criteria are met: • Implantation of the stimulator is used only as a late (if not last) resort for patients with chronic intractable pain; AND • Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not provide satisfactory pain control; AND • Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation (screening must include psychological as well as physical evaluations); AND • Psychological evaluation has been obtained and indicates that the member is a favorable candidate for permanent spinal cord stimulation. Permanent Implantation Permanent implantation of a spinal cord stimulator MAY be covered when a temporary trial has been successful. Successful is defined as: • A temporary trial of at least two days duration has been undertaken with ALL of the criteria listed above met; AND • Demonstration of at least a 50% reduction in pain and improved function with the temporarily implanted electrode prior to the permanent implantation. Note: These criteria for spinal cord stimulators are not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS web site at http://www.cms.hhs.gov/ for additional information.	**POSITIVE**
Kaiser Foundation Health Plan of the Northwest, Inc. - 16,446 covered lives 500 NE Multnomah, Suite 100, Portland, OR 97232 www.kaiserpermanente.org Contracted or Affiliated PBM(s): MedImpact Healthcare Systems, Inc., HealthTrans States Served: Oregon, Washington.	**Excerpt-** Treatment Overview Spinal cord stimulation (SCS) is a procedure that uses an electrical current to treat chronic pain. A small pulse generator, implanted in the back, sends electrical pulses to the spinal cord. These pulses interfere with the nerve impulses that make you feel pain. Implanting the stimulator is typically done using a local anesthetic and a sedative. Your doctor usually will first insert a trial stimulator through the skin (percutaneously) to give the treatment a trial run. (A percutaneous stimulator tends to move from its original location, so it is considered temporary.) If the trial is successful, your doctor can implant a more permanent stimulator. The stimulator itself is implanted under the skin of the belly (abdomen), and the small coated wires (leads) are inserted under the skin to the	**POSITIVE**

Alias(es): Includes Kaiser Permanente Health Alternatives (KPHA Health Plans). Ownership: Kaiser Permanente. Not-for-profit. Private. https://members.kaiserpermanente.org/kpweb/healthency.do?hwid=tn9286	point where they are inserted into the spinal canal. This placement in the abdomen is a more stable, effective location. Most stimulator batteries must be replaced every 2 to 5 years. After this outpatient procedure is complete, you and your doctor determine the best pulse strength. You are then told how to use the stimulator at home. A typical schedule for spinal cord stimulation is to use it for 1 or 2 hours, 3 or 4 times a day. When in use, the spinal cord stimulator creates a tingling feeling, rather than the pain you have felt in the past.	
Lifewise Health Plan of Washington - 87,389 covered lives 7001 220th Street, SW, Building #3, Mountlake Terrace, WA 98043 www.lifewisewa.com Contracted or Affiliated PBM(s): Medco Health Solutions, Inc. States Served: Washington. Ownership: Premera, Inc. Not-for-profit. Private. https://www.lifewisewa.com/lwwa/groups/public/documents/medicalpolicy/cmi_003695.pdf	**Excerpt-** 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 pain therapies, when performed according to policy guidelines. Spinal cord stimulation is considered investigational as a treatment of [redacted]. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations may apply: • The treatment is used only as a last resort, other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated; • Pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, [redacted]. 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 CNS damage from a stroke or spinal cord injury); • No serious untreated drug habituation exists; • Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation; • All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.	**POSITIVE**
Premera Blue Cross - 1,334,000 covered lives 7001 220th Street, SW, Mountlake Terrace, WA 98043 www.premera.com Ownership: Premera, Inc. Not-for-profit. Private Contracted or Affiliated PBM(s): Medco Health Solutions, Inc. States Served: Alaska, Washington. https://www.premera.com/stellent/groups/public/documents/medicalpolicy/cmi_0036	**Excerpt -** 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 pain therapies, when performed according to policy guidelines. Spinal cord stimulation is considered investigational as a treatment of [redacted] Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations may apply: - The treatment is used only as a last resort, other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated; - Pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, [redacted]. Spinal cord stimulation is generally not effective in treating nociceptive pain	**POSITIVE**

95.pdf	(resulting from irritation, not damage to the nerves) and central deafferentation pain (related to CNS damage from a stroke or spinal cord injury); - No serious untreated drug habituation exists; - Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation; - All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.	
Providence Health Plan - 34,215 covered lives 3601 SW Murray Boulevard, Suite 10, Beaverton, OR 97005 www.providence.org/healthplans States Served: Oregon, Washington. Ownership: Providence Health and Services. Not-for-profit. Private. NO LINK AVAILABLE	**Excerpt-** Implantable spinal cord stimulators may be approved subject to benefit and plan criteria listed below on an individual case-by-case basis for patients with chronic intractable radicular pain that have failed all other treatment modality and procedures and who has completed a successful trial for spinal cord stimulator. A prior authorization is required for the spinal cord stimulator trial and if all criteria met the placement of the spinal cord stimulator. All other uses for spinal cord stimulators are not covered. The efficacy has not been established for other painful syndromes such as [redacted]. The following criteria must be met for a spinal cord stimulator trial; - patients with chronic intractable back pain with associated radiating pain who have failed all other treatments and or procedures including multiple surgical interventions. - Psychological assessment may be required. - The use of the stimulator for a particular pain syndrome other than radicular back pain must be supported by scientific medical studies published in relevant medical journals. Final implantation of a spinal cord stimulator may be covered when; - the patient has completed a successful trial of 3-7 days, with a 50% decrease in pain and /or some decrease in medication use. An objective report of the results of the trial must be submitted.	**POSITIVE**
Regence BlueCross BlueShield of Oregon - 3,138 100 SW Market Street, Portland, OR 97207 www.or.regence.com Contracted or Affiliated PBM(s): RegenceRx States Served: Oregon. Ownership: Affiliate of the Regence Group. Not-for-profit. Private. http://blue.regence.com/trgmedpol/surgery/sur45.html	Excerpt- I. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations apply: A. Spinal cord stimulation may be considered medically necessary for the treatment of either of the following conditions and when all patient selection criteria in B. below have been met: 1. Severe and chronic pain of the trunk or limbs other than critical limb ischemia that is refractory to all other pain therapies, or 2. Chronic refractory angina pectoris in patients who are not considered candidates for a revascularization procedure. B. All of the following Patient Selection Criteria must be met: 1. The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated. 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. 3. No serious untreated drug habituation exists. 4. Patient was carefully screened, evaluated and diagnosed by a multidisciplinary pain management team prior to application of these therapies. 5. Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation.	**POSITIVE**

	II. Spinal cord stimulation is considered investigational for all other indications including but not limited to treatment of the following: A. Critical limb ischemia as a technique to forestall amputation B. Visceral pain C. Drug-refractory chronic cluster headaches D. Nociceptive pain (resulting from irritation, not damage to the nerves) E. Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury)	
Regence BlueShield - 991,337 covered lives 1800 Ninth Avenue, P.O. Box 21267, Seattle, WA 98111 www.wa.regence.com Ownership: Affiliate of the Regence Group. Not-for-profit. Private. Contracted or Affiliated PBM(s): RegenceRx States Served: Washington. http://blue.regence.com/trgmedpol/surgery/sur45.html	**Excerpt -** I. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations apply: A. Spinal cord stimulation may be considered medically necessary for the treatment of either of the following conditions and when all patient selection criteria in B. below have been met: 1. Severe and chronic pain of the trunk or limbs other than critical limb ischemia that is refractory to all other pain therapies, or 2. [redacted]. B. All of the following Patient Selection Criteria must be met: 1. The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated. 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, [redacted]. 3. No serious untreated drug habituation exists. 4. Patient was carefully screened, evaluated and diagnosed by a multidisciplinary pain management team prior to application of these therapies. 5. Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation. II. Spinal cord stimulation is considered investigational for all other indications including but not limited to treatment of the following: [redacted]	**POSITIVE**
Regence BlueShield of Idaho - 4,076 1602 21st Avenue, Lewiston, ID 83501 www.id.regence.com Contracted or Affiliated PBM(s): RegenceRx; Postal Prescription Services, Inc. (mail order); Walgreens Mail Service Pharmacy (mail order) States Served: Idaho. Affiliate of the Regence Group. Not-Ownership: for-profit. Private. http://blue.regence.com/trgmedpol/surgery/sur45.html	**Excerpt-** I. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations apply: A. Spinal cord stimulation may be considered medically necessary for the treatment of either of the following conditions and when all patient selection criteria in B. below have been met: 1. Severe and chronic pain of the trunk or limbs other than critical limb ischemia that is refractory to all other pain therapies, or 2. Chronic refractory angina pectoris in patients who are not considered candidates for a revascularization procedure. B. All of the following Patient Selection Criteria must be met: 1. The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated. 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. 3. No serious untreated drug habituation exists. 4. Patient was carefully screened, evaluated and diagnosed	**POSITIVE**

	by a multidisciplinary pain management team prior to application of these therapies. 5. Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation. II. Spinal cord stimulation is considered investigational for all other indications including but not limited to treatment of the following: A. Critical limb ischemia as a technique to forestall amputation B. Visceral pain C. Drug-refractory chronic cluster headaches D. Nociceptive pain (resulting from irritation, not damage to the nerves) E. Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury)	
Tufts Associated Health Plans, Inc. – 84 705 Mt. Auburn Street, Watertown, MA 02472 www.tuftshealthplan.com Contracted or Affiliated PBM(s): Caremark Rx, Inc. States Served: Massachusetts. Telephone (Automated): (800) 462-0224 Ownership: For-profit. Private. http://www.tuftshealthplan.com/providers/pdf/mng/Spinal_Cord_Stim.pdf	Excerpt- Tufts Health Plan may authorize coverage of dorsal column stimulation for members with a diagnosis of chronic back pain due to one of the following: - Failed back surgery syndrome with predominant low back pain and secondary radicular pain. - Complex regional pain syndrome. - Inoperable chronic ischemic limb pain secondary to peripheral vascular disease. - The member must also meet all of the following criteria: - There is a documented pathology that is the objective basis of the pain. - The member has tried and failed conservative methods of pain management.1 - The member is not a candidate for further surgical intervention. - A multidisciplinary team that has evaluated the appropriateness of the device and screened for any untreated existing drug addiction and psychiatric problems has evaluated the member. - The Member%u2019s pain is predominantly radiating extremity pain. - The Member experienced significant pain reduction (50% or more) with a 3-7 day trial of percutaneous spinal stimulation.	**POSITIVE**
WellCare Health Plans, Inc. - 2,977 8735 Henderson Road, Tampa, FL 33634 www.wellcare.com States Served: Florida. Alias(es): Harmony Health Plan; WellCare of Florida; WellCare of New York; WellCare of Georgia; WellCare of Ohio; WellCare of Connecticut; Staywell; HealthEase of Florida, Inc.; WellCare of Arizona; WellCare of Louisiana; WellCare Health Plans of New Jersey; WellCare of Texas; Wellcare of Illinois; Preferred One, First Choice. WellCare Group of	**Excerpt-** Spinal cord stimulation of the dorsal column is considered medically necessary for the relief of chronic (greater than six months) intractable pain caused by the following conditions: -Lumbosacral arachnoiditis that has not responded to medical management including physical therapy (NOTE: Presence of arachnoiditis is usually documented by presence of high levels of proteins in the cerebrospinal fluid and/or by myelography or magnetic Resonance Imaging); OR, -Post-surgical or post-traumatic nerve root injuries, including post-laminectomy syndrome (failed back surgery syndrome [FBSS]); OR, -Complex regional pain syndrome I and II; OR, - Phantom limb syndrome that has not responded to medical management; OR, - End-stage peripheral vascular disease, when the member cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management; OR, - Post-herpetic neuralgia; OR, - Plexopathy; OR, - Intercostal neuralgia that did not respond to medical management and nerve blocks; OR, - Cauda equine injury; OR, - Incomplete spinal cord injury. Spinal cord stimulation of the dorsal column is considered medically necessary for the relief of chronic intractable pain caused by the above conditions if ALL of the following criteria are met: - The implantation is used as a last	**POSITIVE**

Companies. For-profit. Private subsidiary of Ownership: public company. NYSE: WCG http://www.wellcare.com/WCAssets/corporate/assets/HS115_Spinal_Cord_Stimulation_Implant.pdf	resort for members with chronic intractable pain; AND, - Other treatment modalities (pharmacological, surgical, physical) have been tried for a minimum of six months and did not prove satisfactory or are considered unsuitable or contraindicated for the given member; AND, - Further surgical intervention is not indicated; AND, - Psychological evaluation has been obtained and there is documentation clearly stating the pain is not psychologic in origin; AND, - No contraindications to implantation exist such as sepsis or coagulopathy; AND,- There has been a clear demonstration of pain relief (50% reduction) on a 3 to 7 day trial with a temporarily implanted electrode preceding permanent implantation.	

In addition to the private payers listed in the table above, there are other 15 payers that serve Washington residents that had no coverage information available to us. Despite not having specific coverage information for the above list of plans, we were able to review our prior authorization database, which provides some indication of whether the plan has a history of allowing access to SCS. Ten of the 15 private payers without SCS coverage information that were in our prior authorization database have a history of approving access to SCS, while 2 consistently denied prior authorizations, and 3 had no further information. This demonstrates that even for those insurers without a specific coverage policy, the majority are approving access to SCS. In summary, of the 4,311,074 commercially-insured lives in Washington, 3,959,691 (91.8%) are definitely or, at a minimum, anecdotally allowed access to spinal cord stimulation (provided they meet the appropriate patient selection criteria), 6.7% are definitely or, at a minimum, anecdotally denied access to spinal cord stimulation, and for the remaining 1.5%, we have no information.

National Payer and Covered Lives	**SCS Language**	**Coverage**
Wellpoint – 33,855,000 covered lives 120 Monument Circle, Indianapolis, IN 46204 www.wellpoint.com Ownership: WellPoint, Inc. For-profit. Public. Contracted or Affiliated PBM(s): Express Scripts, Inc. States Served: Nationwide. Blue Cross or Blue Shield licensee in the following states: California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York,	**Excerpt -** **Medically Necessary:** A *temporarily* implanted spinal cord stimulator for the treatment of chronic (greater than 6 month duration), intractable neuropathic pain is considered **medically necessary** when ***all*** of the following criteria are met: 1. Documentation in the medical record of the failure of 6 months of conservative treatment modalities (pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated; **and** 2. Further surgical intervention is not indicated; **and** 3. Psychological evaluation has been obtained and there is documentation clearly stating the pain is not psychologic in origin; **and** 4. No contraindications to implantation exist such as sepsis or coagulopathy; **and** 5. Objective documentation of pathology in the medical record. A *permanently* implanted spinal cord stimulator for the treatment of chronic (greater than 6 month duration), intractable neuropathic pain is considered **medically necessary** when a temporary trial of spinal cord stimulation has been successful. Successful is defined as: • 50% reduction in pain for at least 2 days; **and** • Improvement in function documented in the medical record.	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
Ohio, Virginia, and Wisconsin. http://www.anthem.com/ca/medicalpolicies/policies/mp_pw_a053357.htm		
United Healthcare – 31,980,000 covered lives UnitedHealth Group Center, 9900 Bren Road East, Minnetonka, MN 55343 www.uhc.com Ownership: UnitedHealth Group. For-profit, public Contracted or Affiliated PBM(s): Prescription Solutions. States Served: Nationwide. https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/UnitedHealthcare%20Medicare%20Coverage/Stimulators_ElectSpinal_SH_Ovations.pdf	**Excerpt –** Spinal cord stimulator is covered for the following indications. 1) To treat chronic pain caused by lumbosacral arachnoiditis that has not responded to medical management including physical therapy (presence of arachnoiditis is usually documented by the presence of high levels of proteins in the CSF and/or by myelography or MRI); 2) To treat intractable pain caused by nerve root injuries, post-surgical or post-traumatic, including that of post-laminectomy syndrome (failed back syndrome); 3) To treat intractable pain caused by complex regional pain syndrome I and II (term causalgia reflex sympathetic dystrophy changed to complex regional pain syndrome I and II); [Indications 4-10 redacted].	**POSITIVE**
AETNA Health Inc. – 18,180,994 covered lives 1000 Middle Street, Middletown, CT 06156 www.aetna.com Ownership: Aetna Inc. For-profit, public Contracted or Affiliated	**Excerpt-** Aetna considers dorsal column stimulators (DCS) medically necessary durable medical equipment (DME) for the management of members with chronic pain due to: (i) failed back surgery syndrome with low back pain and significant radicular pain, (ii) complex regional pain syndrome (also known as reflex sympathetic dystrophy), or (iii) [indication redacted] and the member meets all of the following criteria: 1. Member does not have any untreated existing drug addiction problems (per American Society of Addiction Medicine (ASAM) guidelines), *and* 2. Member experienced significant pain reduction (50% or	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
PBM(s): Aetna Pharmacy Management (APM) States Served: Nationwide. http://www.aetna.com/cpb/medical/data/100_199/0194.html	more) with a 3- to 7-day trial of percutaneous spinal stimulation. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief), *and* 3. Member has obtained psychiatric clearance, *and* 4. Other more conservative methods of pain management have been tried and failed, and 5. There is documented pathology, i.e., an objective basis for the pain complaint.	
CIGNA HealthCare, Inc. – 11,131,599 covered lives 900 Cottage Grove Road, Bloomfield, CT 06002 www.cigna.com Ownership: Connecticut General Life Insurance Company. For-profit, Public. Contracted or Affiliated PBM(s): CIGNA Pharmacy Management States Served: Nationwide. http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0380_coveragepositioncriteria_spinal_cord_stimulation.pdf	**Excerpt –** CIGNA covers a short-term trial of spinal cord stimulation (SCS) for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when BOTH of the following criteria are met: • There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management. • Appropriate mental health screening has been completed, and there is no evidence of an inadequately controlled mental heath problem. CIGNA covers permanent implantation of a spinal cord stimulator for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when ALL of the following criteria are met: • There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management. • Appropriate mental health screening has been completed, and there is no evidence of an inadequately controlled mental heath problem. • Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation. CIGNA covers a short-term trial of spinal cord stimulation (SCS) for the treatment of pain secondary to [redacted]. CIGNA covers permanent implantation of a spinal cord stimulator for the treatment of pain secondary to [redacted].	**POSITIVE**
Humana, Inc. – 8,359,031 covered lives 500 West Main Street Louisville, KY 40202 www.humana.com Ownership: Humana, Inc. for-profit. Public. Contracted or Affiliated PBM(s): Argus Health Systems, Inc.	**Excerpt-** Humana members **MAY** be eligible under the Plan for **spinal cord stimulation** for the following conditions: • [redacted]; **OR** • Failed back surgery syndrome (FBSS) with primarily radicular pain; **OR** • [redacted]; **OR** • Reflex sympathetic dystrophy (RSD)/complex regional pain syndrome (CRPS). **Temporary Trial** A temporary trial of spinal cord stimulation **MAY** be covered for any of the conditions listed above when **ALL** of the following criteria are met:	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
States Served: Nationwide. http://apps.humana.com/tad/tad_new/Search.aspx?criteria=spinal%20cord%20stimulators&searchtype=freetext	• Implantation of the stimulator is used only as a late (if not last) resort for patients with chronic intractable pain; **AND** • Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not provide satisfactory pain control; **AND** • Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation (screening must include psychological as well as physical evaluations); **AND** • Psychological evaluation has been obtained and indicates that the member is a favorable candidate for permanent spinal cord stimulation. **Permanent Implantation** Permanent implantation of a spinal cord stimulator **MAY** be covered when a temporary trial has been successful. Successful is defined as: • A temporary trial of at least two days duration has been undertaken with **ALL** of the criteria listed above met; **AND** • Demonstration of at least a 50% reduction in pain and improved function with the temporarily implanted electrode prior to the permanent implantation.	
Blue Cross and Blue Shield of Illinois – 7,183,328 covered lives 300 East Randolph Drive Chicago, IL 60601 www.bcbsil.com Ownership: Health Care Service Corporation, a mutual legal reserve company. Not-for-profit. Private. Contracted or Affiliated PBM(s): Prime Therapeutics, Inc. States Served: Illinois. http://medicalpolicy.hcsc.net/medicalpolicy/home?ctype=POLICY&cat=Surgery&path=/templatedata/medpolicies/POLICY/data/SURGERY/SUR712.009_2008-01-15#hlink	**Excerpt-** Spinal cord stimulation (SCS) **may be considered medically necessary** for treating patients with severe and chronic neuropathic pain that is refractory to all other pain therapies, when all of the following criteria are met: 1. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or there is documented clinical evidence that these modalities are unsuitable or contraindicated; AND 2. The pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves, **NOTE:** SCS is not effective for: • nociceptive pain (resulting from irritation, not damage to the nerves); • central deafferentation pain (related to central nervous system (CNS) damage from a stroke or spinal cord injury; AND 3. There is no significant untreated drug habituation or addiction; AND 4. There is documentation of at least 50% pain relief achieved from temporary implanted electrodes prior to permanent SCS implantation. **NOTE**: Common conditions that cause severe, chronic, refractory neuropathic pain include, but are not limited to: • Failed back syndrome; • Complex regional pain syndrome (i.e., reflex sympathetic dystrophy); • Arachnoiditis; • Radiculopathies;	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
	• [redacted]; • [redacted].	
Health Net, Inc. – 6,659,000 covered lives 21650 Oxnard Street, Woodland Hills, CA 91367 www.healthnet.com Ownership: Health First, Inc. For-profit. Private. States Served: Primarily Arizona, California, Connecticut, New Jersey, New York and Oregon. TRICARE North Contract in 23 states. https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/dorsal_column_stimulators_apr_08.pdf	**Excerpt-** Health Net, Inc. considers dorsal column stimulation (DCS) medically necessary when all of the following are met: -The implantation of the stimulator is used only as a last resort for patients with chronic intractable pain; -Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient; -Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation); -All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient must be available; and -Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation. -Patients with chronic intractable pain due to any of the following: -Lumbosacral adhesive arachnoiditis secondary to multiple myelographies or lumbar surgeries that has not responded to medical management, including physical therapy (the presence of arachnoiditis is usually documented by the presence of high levels of proteins in the CSF and/or by myelography or MRI.); -Nerve root injuries, post surgical or post traumatic (e.g., avulsion), including that of post-laminectomy syndrome (failed back syndrome); -Complex regional pain syndrome I & II (term causalgia reflex sympathetic dystrophy changed to complex regional pain syndrome I & II); -[redacted].	**POSITIVE**
Kaiser Foundation Health Plan, Inc. – 6,657,444 covered lives One Kaiser Plaza, 300 Lakeside Drive Oakland, CA 94612 www.kp.org Ownership: Kaiser Permanente. Not-for-profit. Private Contracted or Affiliated PBM(s): MedImpact Healthcare Systems, Inc., HealthTrans . States Served: California.	**No Published Policy -No anecdotal evidence**	

National Payer and Covered Lives	SCS Language	Coverage
Blue Cross Blue Shield of Michigan – 4,548,575 covered lives 600 East Lafayette Boulevard, Detroit, MI 48226 www.bcbsm.com Ownership: Blue Cross Blue Shield of Michigan. Not-for-profit, Private Contracted or Affiliated PBM(s): Medco Health Solutions, Inc; MedImpact Healthcare Systems, Inc. States Served: Michigan.	**No Published Policy** Anecdotal evidence supports favorable coverage policy based on history of 25 cases which were submitted to BCBS of MI for "pre-determination". Cases were formally reviewed and approved for the following diagnosis codes. 337.22 Reflex sympathetic dystrophy of the lower limb (complex regional pain syndrome type 1) 338.4 Chronic pain syndrome 722.52 Radiculitis due to degenerative disc disease, lumbar 722.83 Postlaminectomy syndrome, lumbar region (failed back syndrome) 724.4 Radicular syndrome of lower limbs	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
Blue Cross Blue Shield of Texas – 4,381,522 covered lives 901 S. Central Expressway, Richardson, TX 75080 www.bcbstx.com Ownership: Health Care Service Corporation, a mutual legal reserve company. Not-for-profit. Private. Contracted or Affiliated PBM(s): Prime Therapeutics, LLC States Served: Texas. http://www.bcbstx.com/provider/index.htm	**Excerpt-** Spinal cord stimulation (SCS) may be considered medically necessary for treating patients with severe and chronic neuropathic pain that is refractory to all other pain therapies, when all of the following criteria are met: 1. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or there is documented clinical evidence that these modalities are unsuitable or contraindicated; AND 2. The pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves, NOTE: SCS is not effective for: • nociceptive pain (resulting from irritation, not damage to the nerves); • central deafferentation pain (related to central nervous system (CNS) damage from a stroke or spinal cord injury; AND 3. There is no significant untreated drug habituation or addiction; AND 4. There is documentation of at least 50% pain relief achieved from temporary implanted electrodes prior to permanent SCS implantation. NOTE: Common conditions that cause severe, chronic, refractory neuropathic pain include, but are not limited to: • Failed back syndrome; • Complex regional pain syndrome (i.e., reflex sympathetic dystrophy); • Arachnoiditis; • Radiculopathies; • [redacted]; • [redacted].	**POSITIVE**
Coventry Health and Life Insurance Company - 3,603,910 covered lives 6705 Rockledge Drive, Suite 900, Bethesda, MD 20817 www.coventryhealthcare.com Ownership: Coventry Health and Life Insurance Company. For-Profit, Public States Served: Nationwide.	**No Published Policy-** Anecdotal evidence supports favorable coverage policy based on history of 19 cases which were submitted to Coventry Health and Life for “pre-determination”. Cases were formally reviewed and approved for the following diagnosis codes. 722.10 722.83 724.4 337.22	**POSITIVE**

National Payer and Covered Lives	SCS Language	Coverage
Blue Cross and Blue Shield of Alabama - 3,570,223 covered lives 450 Riverchase Parkway East, Birmingham, AL 35244 www.bcbsal.com Ownership: Blue Cross and Blue Shield of Alabama. Not-For-Profit, Private States Served: Alabama. https://www.bcbsal.org/providers/policies/final/328.pdf	**No Published Policy-** Spinal cord stimulation meets Blue Cross and Blue Shield Alabama's medical criteria for coverage for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies, when all of the following criteria, clearly documented in the patient's record, are met: • The implantation of the stimulator is used only as a late or last resort for patients with chronic pain (present for ≥ three months); and • Other treatment modalities (pharmacological, surgical, physical or psychological therapies) have been tried and did not prove satisfactory or are judged unsuitable or contraindicated for the given patient; and • Patient has undergone careful screening evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening includes psychological as well as physical evaluation; psychological testing that demonstrates the patient is not a suitable candidate for the procedure will exclude coverage for that patient.); and • All of the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, training, and follow-up of the patient must be available; and • Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation (revision or replacement of the pulse generator, electrodes or receiver does not require a trial).	**POSITIVE**

The top 10 private payers in the U.S. provide access to SCS for a minimum of 133,453,182 commercially-insured lives.

Appendix #6: Mortality Statistics for Oral Opioid Use and Spine Surgery

Citation/Source	Procedure/Treatment	Mortality Statistics
Juratli et al. Mortality after lumbar fusion surgery. Spine 2009;34(7):740-747. Retrospective population-based cohort study of Washington State WC claimants (2,378)	Lumbar fusion surgery	• 0.29% 90-day perioperative mortality rate (95% CI:0.11%-0.60%) • Age- and gender-adjusted all-cause mortality rate was 3.1 deaths/1,000 worker-years. (95% CI:0.9-9.8)
Wang MC, et al. Complications and mortality associated with cervical spine surgery for degenerative disease in the United States. Spine 2007;32(3):342-7. Retrospective nationwide database study (NIS) of 932,009 cases.	Cervical spine surgery for degenerative disc disease	• Mortality rate (in-hospital) varied by type of surgical procedure. • Anterior decompress = 0.10% • Anterior fusion = 0.11% • Posterior decompress = 0.30% • Posterior fusion = 0.44% • Combined anterior posterior fusion = 0.40%
Kim HJ, et al. Life expectancy after lumbar spine surgery. One to eleven year follow-up of 1,015 patients. Spine 2008;33:2116–2121. Retrospective cohort study of 1,015 patients at one center.	Lumbar spinal surgery for spinal stenosis	• In the study group of patients who underwent spine surgery, the 10-yr survival was 94%.
Franklin GM, Mai J, Wickizer T, Turner JA, Fulton-Kehoe D, Grant L. Opioid dosing trends and mortality in Washington State workers' compensation, 1996-2002. Am J Ind Med 2005;48(2):91-99. An examination of opiate prescriptions and dosing patterns (from computerized databases, 1996 to 2002), and accidental poisoning deaths attributable to opioid use (from death certificates, 1995 to 2002), in the Washington State workers' compensation system.	Opioids	• Opioid prescriptions increased only modestly between 1996 and 2002. However, prescriptions for the most potent opioids (Schedule II), as a percentage of all scheduled opioid prescriptions (II, III, and IV), increased from 19.3% in 1996 to 37.2% in 2002. Among long-acting opioids, the average daily morphine equivalent dose increased by 50%, to 132 mg/day. Thirty-two deaths were definitely or probably related to accidental overdose of opioids.
Increase in poisoning deaths caused by non-illicit drugs—Utah, 1991-2003. MMWR Morb Mortal Wkly Rep 2005;54(2):33-6. An examination of Medical Examiner data in Utah residents	All drugs, non-illicit including opioids	During 1991-2003, the number of Utah residents dying from all drug poisoning increased nearly fivefold, from 79 deaths in 1991 (rate: 4.4 per 100,000 population) to 391 deaths in 2003 (rate: 16.6). This increase has been largely the result of the tripling of the rate (from 1.5 during 1991-1998 to 4.4 during 1999-2003) in poisoning deaths of unintentional or

		undetermined intent caused by non-illicit drugs (i.e., medications that can be legally prescribed).

Appendix #7: Other Literature Addressing SCS-related Adverse Events

Citation/Source	Adverse Events Reported
Turner JA, et al. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain* 2004;108:137-147.	• Any complication: mean 34.3%, median 40% • Superficial infection: mean 4.5%, median 4.0% • Deep infection: mean 0.1%, median 0% • Pain in region of stimulator components: mean 5.8%, median 0% • Biological complications other than infection or local pain: mean 2.5%, median 0% • Equipment failure: mean 10.2%, median 6.5% • Stimulator revision for reasons other than a battery change: mean 23.1%, median 21.5% • Stimulator removal: mean 11%, median 6.0% • *No reported mortality in this systematic review of the literature.*
Cameron T, et al. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg (Spine 3)* 2004;100:254–267.	• Lead migration: incidence 13.2% • Infection: incidence 3.4% • Epidural hemorrhage: incidence 0% • Seroma: incidence 0% • Hematoma: incidence 0.3% • Paralysis: incidence 0.03% • CSF leak: incidence 0.3% • Unwanted stimulation: incidence 2.4% • Intermittent stimulation: incidence 0% • Pain over implant: incidence 0.9% • Allergic reaction: incidence 0.1% • Skin erosion: incidence 0.2% • Lead breakage: incidence 9.1% • Hardware malfunction: incidence 2.9% • Loose connection: incidence 0.4% • Battery failure: incidence 1.6% • Other: incidence 1.4% • *No reported mortality in this systematic review of the literature.*

Appendix #8: ISPR SCS Product Performance-related Events

EVENTS	NO.	TIME TO EVENT IN MONTHS	
Neurostimulator Related Events:			
Broken bond wire*	1	49.6 (49.6) ±NA	
Loss of effect†	1	21.1 (21.1) ±NA	
Recharging issue	1	1.8 (1.8) ±NA	
Undesirable change in stimulation‡	2	22.1 (22.1) ±22.7	
Neurostimulator Related Events Sub-Total	5	23.3 (21.1) ±20.5	
Lead Related Events:			
Electrode contact damage	3	40.7 (25.1) ±27.0	
Disconnection	1	0.9 (0.9) ±NA	
Lead wire fracture	32	18.8 (17.7) ±10.5	
Migration/dislodgement	77	11.7 (4.4) ±15.9	
Undesirable change in stimulation	44	17.0 (4.6) ±23.5	
Lead Related Events Sub-Total	157	15.1 (7.1) ±18.2	
Extension Related Events:			
Extension failure§	3	4.0 (3.2) ±3.1	
Fracture	8	20.2 (20.8) ±8.9	
Extension Related Events Sub-Total	11	15.8 (13.6) ±10.7	
Product Performance Related Events Total	173	15.4 (7.4) ±17.8	

Appendix #9: ISPR SCS Non-product Performance-related Events

EVENTS	NO.	TIME TO EVENT IN MONTHS
Surgical/Procedural Related Events:		
Neurostimulator Pocket/Access Related		
Hematoma	1	12.4 (12.4) ±NA
Infection	22	7.8 (4.3) ±9.2
Migration/inversion	11	19.9 (18.4) ±15.6
Pain at site	19	9.3 (8.7) ±5.4
Seroma	3	15.6 (13.2) ±7.6
Skin erosion	3	6.1 (3.9) ±4.3
Wound dehiscence	1	15.9 (15.9) ±NA
Neurostimulator Pocket Related Sub-Total	60	11.0 (8.5) ±10.3
Lead Tract Related		
Infection	5	10.9 (4.3) ±10.7
Pain at site	6	10.3 (9.8) ±4.1
Skin erosion	3	13.5 (6.7) ±14.6
Lead Tract Related Sub-Total	14	11.2 (9.0) ±8.7
Extension Tract Related		
Body fluids entry into connection	1	12.5 (12.5) ±NA
Extension Tract Related Sub-Total	1	12.5 (12.5) ±NA
Surgical/Procedural Related Events Sub-Total	75	11.1 (8.9) ±9.9
Therapy/Patient Related Events:		
Therapy/Patient Effects		
Allergic reaction	1	9.6 (9.6) ±NA
Corrective surgery*	6	16.4 (15.3) ±11.5
Cosmetic issue†	2	10.3 (10.3) ±11.3
Infection	4	9.7 (10.8) ±7.3
Leg pain/weakness	1	28.6 (28.6) ±NA
Loss of effect	13	17.4 (15.6) ±13.4
Needed expanded coverage‡	3	15.7 (10.6) ±10.2
No anomaly found by RPA§	1	19.5 (19.5) ±NA
Pain/irritation	1	9.3 (9.3) ±NA
Patient choice‖	1	0.9 (0.9) ±NA
Patient non-compliance¶	1	17.9 (17.9) ±NA
Psychological issue	3	15.6 (17.3) ±9.3
Resolution of symptoms**	3	20.2 (23.3) ±8.8

Therapy didn't meet patient's expectations	59	15.9 (12.2) ±11.9
Undesirable change in stimulation	2	14.6 (14.6) ±7.3
Undesirable interaction with other equipment	8	9.2 (7.7) ±6.2
Therapy/Patient Related Events Sub-Total	109	15.3 (12.4) ±11.1
Patient Related Events:††		
Patient Expired	23	16.8 (12.6) ±16.3
Patient lost to follow-up	132	16.1 (12.6) ±14.8
Patient Related Events Sub-Total	155	16.2 (12.6) ±15.0
Normal Battery Depletion Events:		
Battery Depletion	140	28.0 (26.5) ±14.2
Battery Depletion Events Sub-Total	140	28.0 (26.5) ±14.2
Non-Product Performance Related Events Total	479	18.6 (14.9) ±14.6

Appendix #10: CRPS Outcomes Related to Timing of SCS Implant

1) Kumar K, et al. Wait-times and Its Effect on Spinal Cord Stimulation. Abstract included in the 2009 North American Neuromodulation Society Annual Meeting. Las Vegas, Nevada. December 3-6.

Abstract: (Available in NANS program book)

Introduction: Currently, there is no published data into wait-times for spinal cord stimulation and no benchmarks have been set. Lengthy wait-times lead to deterioration of health, patient dissatisfaction and an increased cost to society. Current literature indicates the average patient waits 5 years for spinal cord implant, with a success rate of 48%. The efficacy of spinal cord stimulation is inversely related to the wait-time. Our goal is to evaluate our current wait-times and determine a wait-time benchmark, and to use this benchmark to ensure ongoing delivery of a quality, patient-centered service. Methods: A retrospective study of 171 spinal cord stimulation patients over a 29 year period was performed. Wait-times from initial referral to specialist and specialist to implant were studied. Other parameters evaluated include time required for further investigations, differences in wait-time depending on referral source, and duration of pain. Results: The mean duration of pain symptoms was 5.6 years (1-40 years). Average time from initial referral to specialist appointment was 3.3 months (1 week – 1 year). From decision to treat to treatment, the mean wait-time was 4.0 months (1 week – 3 years). 46% of patients required further investigations before decision to treat. Time required to these investigations averaged 7.7 months. For patients not requiring further investigations, the average delay from initial referral to treatment is 7.6 months. In comparison, for patients requiring further investigations, the average delay was 15.4 months. Through increased awareness, patients referred in the last five years demonstrated an improvement in wait-time from 7.7 to 5.7 months and a correlative improvement in success rate. Patients refereed from anesthesia pain centers obtained specialist appointment in a shorter amount of time, required fewer further investigations, and obtained treatment in a shorter time. However, patients referred from anesthesiologists have a longer pain duration, compared to neurologists' patients, who have a shorter duration of pain and are referred more quickly for consideration of implantation. Conclusions: Currently our patients wait between 6 and 7 years from the initial onset of pain to implantation. We propose that patients should be implanted within 4-6 months of initial referral, and ideally between 2-5 years from onset of pain. These goals can be achieved by: 1. Expediting referral by educating physicians that SCS is a viable and effective treatment option for the management of chronic nonmalignant pain. 2. Improving acceptance of the procedure and increasing funding by various agencies. 3. Promoting further research.

2) Kumar K, et al. Data presented at podium session during the 2009 North American Neuromodulation Society Meeting. Las Vegas, Nevada. December 3-6.

Notes: Twenty-five patients with CRPS and implanted with SCS were followed for a mean of 87.9 months. Ten patients had an upper limb affected. Fifteen patients had a lower limb affected. Stage 1, Stage 2, and Stage 3 patients were included in the series. Only Stage 1 patients were gainfully employed. A variety of outcome measures were collected (VAS, BDI, ODI, EQ-5D, SF-36) such that pain, function, mental health, quality of life, and health utilities could be assessed. After multivariate regression modeling, the data show that delaying implant of SCS beyond 12 months is significantly associated with increased pain, increased depression, decreased function and decreased status.

Appendix #11: US SCS Cost-Effectiveness Data Presented at 2010 HTAi Conference

Spinal cord stimulation in the treatment of failed back surgery syndrome: Cost-effectiveness in the United States

HTAi 2010. Maximising the Value of Health Technology Assessment
7th - 9th June 2010 - RDS, Dublin, Ireland

Rod S Taylor[1], Anthony Bentley[2], Richard North[3], Jane Shipley[4]

[1]Peninsula Medical School, Universities of Exeter and Plymouth; [2]Abacus International, Bicester, United Kingdom;
[3]The Sandra and Malcolm Berman Brain & Spine Institute, Sinai Hospital of Baltimore, Baltimore, Maryland, United States; [4]The Neuromodulation Foundation, Inc., Baltimore, Maryland, United States

BACKGROUND

In 10 to 40% of patients, lumbosacral spine surgery results in recurrent or persistent pain, a condition referred to as "failed back surgery syndrome" (FBSS). Patients with FBSS often become disabled, have a diminished health-related quality of life, and incur high healthcare costs.

Randomised controlled trials (RCTs) have demonstrated that spinal cord stimulation (SCS) achieves significant pain relief and improves the functional status and health-related quality of life of FBSS patients [1, 2].

The National Institute for Health & Clinical Excellence (NICE) recently prioritised SCS for a technology appraisal. Following a detailed assessment of clinical and cost-effectiveness evidence, NICE recommended SCS in the routine management of FBSS patients refractory to conventional management (TA 169, Oct 2009. http://www.NICE.org.uk).

Although NICE guidance can have an international impact on the implementation of a health technology, there are challenges in transferring cost-effectiveness evidence from one national setting to another. Therefore, we adapt the United Kingdom-based cost-effectiveness analysis to the perspective of the United States (US) and explore the impact of differences in healthcare costs and practice patterns.

METHODS

CHOICE OF COMPARATOR

In Europe, conventional medical management (CMM), which can include pain medication, physical and psychological rehabilitation, is a common approach to the management of FBSS. In the US, however, patients often undergo a repeat operation. In the current analysis, comparisons were, therefore, chosen to reflect both policy options for the use of SCS: (1) SCS versus reoperation and (2) SCS versus CMM alone (we assume that CMM would accompany SCS therapy and reoperation in each scenario).

MODEL STRUCTURE

We used the cost-utility model developed (in MS Excel®) for the NICE Appraisal Programme [3], consisting of a two-stage process: (1) a decision tree reflecting possible initial 6-month responses to SCS based on RCTs, and (2) a Markov model that simulates costs and quality-adjusted life years (QALYs) over a 15-year time horizon, which is within the range of long-term observational SCS data. In this model, patients can experience one of six mutually exclusive health states: optimal pain relief (at least 50% reduction from baseline) with or without SCS-related complications; sub-optimal pain relief (less than 50% but more than zero) with or without complications; no pain relief; or death. During each 3-month Markov cycle, patients allocated to SCS are assumed to remain in their health state unless they: (1) experience a complication, (2) move from optimal to sub-optimal pain relief, (3) move to no pain relief (and switch to CMM or re-operation), or (4) die.

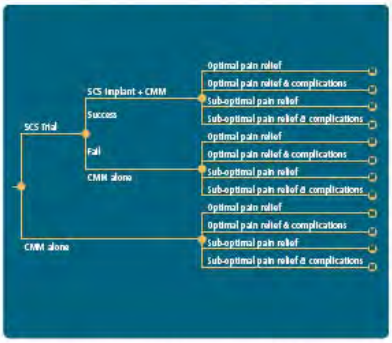
MODEL PARAMETERS

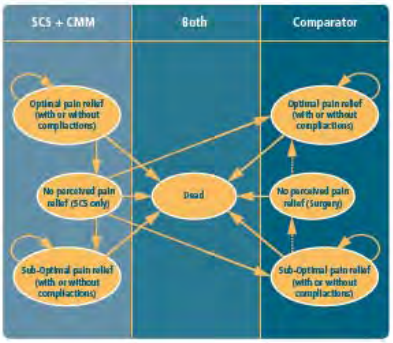
We take the perspective of a healthcare payer. Probabilities of clinical events and EQ-5D data were sourced from RCTs, systematic reviews, and long-term observational data sources. US costs were obtained from MarketScan® research databases. Patients with a diagnosis of FBSS (ICD9 dx 722.83) were identified by the implantation of an SCS generator (CPT 63685 or ICD9 px 03.93), a re-operation, or neither. Costs of SCS-related complications were sourced from a recent retrospective analysis by Kumar & Bishop [4].

REFERENCE CASE

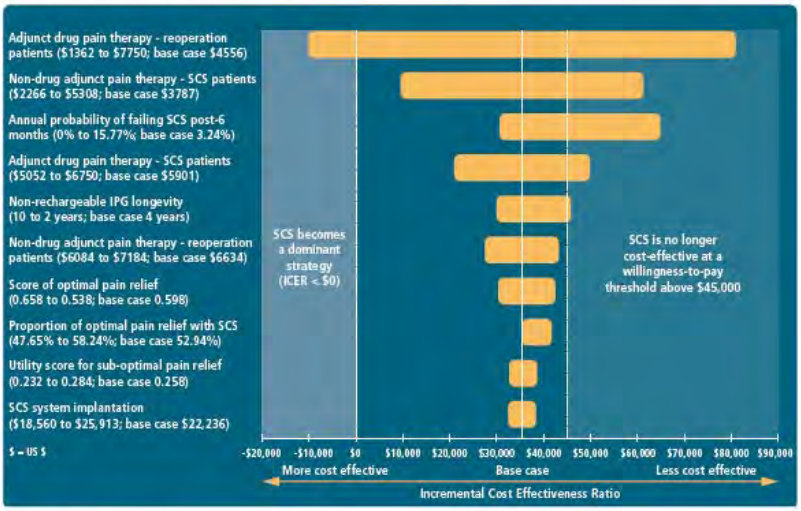
Results are presented as incremental costs and QALYs in 2009 US dollars (see Tables). In accordance with the current US reference case for economic evaluations [5], a discount rate of 3.5% was applied to both costs and health benefits. The uncertainty in model inputs was assessed using probabilistic sensitivity analyses.

DECISION ANALYTIC MODEL STRUCTURE





RESULTS: ONE-WAY SENSITIVITY ANALYSIS - SCS vs. Reoperation



RESULTS: BASE CASE

SCS vs. Reoperation

	Cost/Patient (US $)	QALYs/Patient	ICER (US $)
SCS	$287,301	5.13	-
Reoperation	$252,381	4.15	-
Difference	$34,921	0.98	$35,675

68% probability that SCS is cost-effectiveness at a maximum willingness-to-pay threshold of US $50,000/QALY

SCS vs. CMM

	Cost/Patient (US $)	QALYs/Patient	ICER (US $)
SCS	$166,277	5.13	-
CMM	$139,162	4.15	-
Difference	$27,115	0.98	$21,701

97% probability that SCS is cost-effectiveness at a maximum willingness-to-pay threshold of US $50,000/QALY

CONCLUSIONS

This provisional analysis shows that, from the perspective of the US healthcare payer, SCS appears to a cost-effective option for selected FBSS patients.

Compared with both re-operation and CMM alone, SCS achieved an incremental cost-effectiveness ratio below a willingness-to-pay threshold of US $50,000 per QALY.

The cost-effectiveness of SCS appears to be particularly sensitive to the use, and therefore the cost, of adjunctive medical therapy. We plan to examine this issue more closely in our future modeling analyses.

REFERENCES

1. North RN et al. Neurosurgery 2005;56:98-106
2. Kumar K et al. Pain 2007;132:179-188
3. North RN et al. Clin J Pain 2010 [in press]
4. Kumar K, Bishop S. J Neurosurg Spine. 2009;10:564-73
5. Weinstein MC et al. JAMA 1996;276:1253-1258

This work was supported through funding by Medtronic. The interpretation of the data and conclusions of this study are entirely those of the authors.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK

St. Jude Medical
Neuromodulation Division
6901 Preston Road
Plano, TX 75024
Tel 972 309 8000
Fax 972 309 8150

July 16, 2010

Submitted Electronically: shtap@hca.wa.gov

Brian Budenholzer, MD, FAAFP—Chairman
Health Technology Clinical Committee
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

RE: HTA Draft Report: Spinal Cord Stimulation (June 25, 2010)

Dear Dr. Budenholzer:

On behalf of St. Jude Medical Neuromodulation Division, we are submitting the following comments regarding the June 25, 2010 HTA Draft Report on Spinal Cord Stimulation. We appreciate the opportunity to review this draft report, prepared for the Health Technology Assessment Program by Spectrum Research, Inc., and to share our views on its contents and findings. We recognize the challenges and complexities in conducting technology assessments, and we provide these comments with the intent of strengthening the report and increasing its value to the Health Technology Clinical Committee.

In our review, we noted certain issues (detailed below) associated with the contractor's evaluation of the literature on the use of spinal cord stimulation (SCS) to treat chronic pain that could result in an inaccurate assessment of this technology. Given this, we urge the Health Technology Clinical Committee not to proceed with a coverage determination for this medical procedure until the contractor can address the issues raised and revise the report in light of them.

St. Jude Medical

St. Jude Medical is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. The company has four major product focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular, and neuromodulation.

Specific Comments

Our comments on the draft report touch on three matters: (1) the judgments made by the contractor in grading the clinical information and studies reviewed for the report; (2) the characterization in the report of the purpose and use of SCS therapy; and (3) information that should be considered in an assessment of SCS in order to provide a full evidentiary review of the literature.

1. Questionable Contractor Judgments in Grading Evidence

In reviewing the draft report, we found certain irregularities associated with the grading of evidence bearing on certain of the four Key Questions that were posed:

1. What is the evidence of efficacy and effectiveness of spinal cord stimulation?
2. What is the evidence of safety of spinal cord stimulation?
3. What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub-populations?
4. What is the evidence of cost implications and cost-effectiveness of spinal cord stimulators?

First, we found the grades assigned by the contractor concerning the strength of evidence bearing on the four Key Questions addressed in this report to be inconsistent with the contractor's explanation in Appendix D of the general scoring approach used. The report does not make clear how the individual studies were evaluated and graded for the four Key Questions. This lack of clarification undermines the scientific integrity of the report by preventing the reader from distinguishing fact from opinion.

For example, in considering the "efficacy" and "effectiveness" of spinal cord stimulation (Key Question 1), the contractor cited a single prospective cohort study (Level III evidence) to discount the impact of several randomized controlled clinical trials (Level I and Level II evidence). This cohort study was cited as the sole reason for assigning a "low" evidence grade for the "effectiveness" of SCS.

The report does not explain why the available randomized controlled trial (RCT) data is not considered in addressing the "effectiveness" of SCS. Although some of these trials were conducted in academic settings, these studies used standard practice guideline in selecting patients and the results are applicable to normal practice. In fact, our understanding is that the patients treated with SCS in the single prospective cohort study did not undergo screening procedures typical for those receiving this therapy—a fact which undercuts the use of this study to determine "effectiveness" of the therapy in real world settings.

We believe that it is appropriate to consider both the "efficacy" and the "effectiveness" of medical procedures in assessments such as this, but we do not think that RCT data should be summarily dismissed as being non-representative of normal practice. A proper assessment demands a familiarity with the medical procedure, practice patterns, and factors like operator skill or patient characteristics that may influence results. We believe that the available RCT data should have been used to address both "efficacy" and "effectiveness." If the contractor disagrees

with this, and chooses not to consider this Level I evidence, he should make the case for his judgment in the report, so that the reader is made aware of the rationale that was used. Nevertheless, we believe that a fair grading of the evidence would indicate a grade of "moderate" (instead of "low") for the "effectiveness" of SCS.

The contractor's reliance on the single prospective cohort study in this area should also be questioned because of a series of study limitations which the contractor cites in the report (see the discussion on pages 74 and 77). We find it troubling that the contractor can rely on this study to conclude that there is only "low" evidence of SCS effectiveness when the report also states that cohort studies have a potential for selection bias that can threaten the validity of a study, that there were differences in the SCS group and the other groups treated in the cohort study "in potentially important ways," and that differences in the groups studied were such that "outcomes may have been affected."

We believe that the methodological problems associated with the single prospective cohort study go even further than what the contractor identifies, and we urge the Health Technology Clinical Committee to pay close attention to the evidence grades assigned to SCS "efficacy" and "effectiveness." Because this single prospective cohort study concentrates on the subpopulation of patients who are workers' compensation claimants, we think that this study is best used to address Key Question 3

A second irregularity we found concerns the contractor's approach to addressing Key Question 2 (dealing with safety) and Key Question 3 (dealing with efficacy or safety issues in subpopulations). For each of these Key Questions, the contractor has chosen to focus on grading evidence on matters that could give a distorted view to the reader of the evidence supporting SCS procedures.

For example, the contractor includes "mortality" as one of three factors to examine in the literature (along with "revisions" and "other SCS side effects"). We question the inclusion of this factor because mortality is not an adverse event that has been attributed to SCS therapy, and it has never been reported in the literature or the FDA medical device reporting database with respect to this procedure or to SCS devices. Further, we find the contractor's grade for the evidence—"high"—to be an arbitrary one. The contractor notes that death occurred among certain patients who participated in SCS studies, though none were attributed to the SCS procedure. We can only speculate why the contractor chose to assign a "high" evidence grade to mortality when there are no SCS-induced deaths cited in the literature.

Inclusion of this matter in a discussion of the safety of the SCS procedure—and the "high" evidence grade assigned to it—appears to us to be highly inappropriate, and it calls into question the impartiality of the contractor. As currently written, the report can be read as implying that convincing evidence exists that SCS and mortality are linked, though this is not the case.

In this same vein, we note that the contractor, in addressing Key Question 3 (dealing with efficacy or safety issues in subpopulations) examines an assortment of characteristics, ranging from age and sex (which we would expect) to a variety of clinical and non-clinical characteristics (including insurance coverage). Most received low evidence scores, indicating that there was no "moderate" or "high" level of evidence that the factors were associated with improved outcomes following the SCS procedure.

This is another case where a reader might draw the wrong conclusion from the report—that there was no evidence of beneficial impact, because no "high" level of evidence documented an impact for the various factors identified. We question the inclusion of the long listing of characteristics identified in answering Key Question 3, and we request that the contractor revise the report to provide a more full discussion of the reason for the listing, and make the point that Level I evidence documents the favorable impact of this procedure, though little evidence exists on its impact on particular subpopulations.

A third irregularity associated with the grading of evidence by the contractor relates to the sponsorships of certain of the studies cited. The contractor appears to discount the results of high-quality studies merely because they were sponsored by a manufacturer. At the same time, the contractor cites a study commissioned by the Washington State Department of Labor (which has clear financial interests in the result) to be "a well conducted cohort study" (page 74), and, as mentioned above, relies on it exclusively, despite methodological flaws, to support a low evidence grade for SCS "effectiveness." This approach by the contractor casts question on the impartiality of the contractor's analysis and the scientific rigor of the report.

We urge the Health Technology Clinical Committee to focus on the methodological strengths and weaknesses of the evidence bearing on the four Key Questions posed for this assessment, and not to presume bias in industry-supported studies. Evidence-based results should not be dismissed or discounted because of study sponsorship.

2. Characterization of the Purpose and Use of SCS Therapy

In our review of the draft report, we noted certain areas where the contractor may have mischaracterized the objective of the SCS procedure, and where the report would be enhanced with a more complete explanation of when the procedure is used. These include:

- Pages 7 & 22: "The aim of treatment for chronic pain is to improve function and quality of life while relieving pain." The desired endpoint is the reduction in pain, and this should be the main determinant of the procedure's efficacy and effectiveness. Other endpoints, like quality of life, improved function, reduction in drug use, and return to work are secondary to pain reduction. To group these various possible endpoints has the effect of distorting the evaluation of the evidence at hand.

- Pages 7; 22-23: "Spinal cord stimulation (SCS) is usually not considered as a treatment for neuropathic pain until conventional therapies have failed to provide adequate pain relief." This statement should be expanded to make clear that in current medical practice—and in most insurer coverage policies—a spinal cord stimulator is implanted only as a last resort for patients with chronic intractable pain. Physical, psychological, pharmacological, and surgical therapies must have been tried and found to be unsatisfactory in treating the patient (or found to be unsuitable or contraindicated for the given patient) before considering SCS. Once SCS is considered as a treatment option, the patient typically undergoes a psychological evaluation to be considered for SCS. Further, before permanently implanting an SCS system, physicians must demonstrate that temporarily implanted electrodes provide adequate pain reduction during a 5-7 day evaluation period.

3. Additional Information That Should Be Included in the Report

In our review of the report, we noted that certain materials bearing on the Key Questions posed were omitted.

- American Society of Anesthesiologists, Practice Guidelines for Chronic Pain Management, An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine, *Anesthesiology*, Vol. 112, No. 4 (April, 2010). This evidence-based guideline should have been used to inform the response to each of the Key Questions.

- National Institute for Health and Clinical Excellence, Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischaemic Origin, NICE Technology Appraisal Guidance 159 (October, 2008). Although the contractor made reference to an unpublished study of SCS prepared by the School of Health and Related Research (ScHARR) at the University of Sheffield for the United Kingdom's National Institute of Health and Clinical Excellence (NICE), this material was used only in considering Key Question 4 (dealing with the cost-effectiveness of SCS). The contractor did not include the full technology assessment in its consideration of Key Questions 1, 2, and 3. The contractor should use the full technology assessment, or the NICE document referenced here that is based on this full assessment, in reconsidering the evidence bearing on Key Questions 1, 2, and 3.

*****

Thank you for considering our comments. Given the potential impact of this assessment on the medical care that is made available to patients with chronic neuropathic pain, we trust that you and the Health Technology Clinical Committee will give full consideration to our comments on the draft report.

If you have any questions on our comments, do not hesitate to contact me directly.

Sincerely,

Tracy Cameron, PhD
Vice President Clinical Affairs
& Chief Science Officer

cc: Leah Hole-Curry Program Director

July 15, 2010

Brian R. Budenholzer, MD – Chair, Health Technology Clinical Committee
Washington State Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Via email: shtap@hca.wa.gov

Dear Dr. Budenholzer and Members of the Health Technology Clinical Committee:

On behalf of the Neuromodulation Therapy Access Coalition (NTAC), I wish to provide the following comments on the Washington State Health Technology Assessment (HTA) program's draft evidence report on spinal cord stimulation (SCS). By way of background, NTAC is a national coalition of physician societies representing pain physicians, consumer advocates, and manufacturers of neuromodulation therapies.

Spinal cord stimulation has been used for the treatment of chronic pain since 1967; in particular for failed back surgery syndrome (FBSS) (chronic lumbar pain and lower leg pain after lumbar spine surgery) and complex regional pain syndrome type 1 (CRPS-I; burning pain radiating from the lower back through legs). Randomized controlled trials (RCTs) in FBSS and CRPS patients have demonstrated that SCS can provide statistically significant and clinically meaningful improvement in pain compared to conventional medical management, reoperation, and physical therapy (Kumar K, et al. Pain 2007; Kumar K, et al. Neurosurgery 2008; North RB, et al. Neurosurgery 2005, Kemler MA, et al. NEJM 2000; Kemler MA, et al. Ann Neurol 2004).

We commend the evidence vendor, Spectrum, for developing an extensive overview of the literature on SCS. However, the report contains some significant errors that skew the evidence on SCS and could lead to an inaccurate assessment of SCS and its clinical role in treating patients with certain chronic pain conditions.

We offer the following specific comments concerning the draft evidence report.

1. Despite the lack of any reported incidents in the literature of mortality directly attributable to SCS, it is unclear why the evidence vendor rates the quality of evidence on mortality as "high," based on two deaths – neither of which was attributable to SCS. **We strongly recommend that the evidence vendor and the HTCC amend the presentation of mortality in the summary of evidence addressing question 2 (page 16) and Table 11 (page 125) to emphasize the absence of SCS-related mortality and ensure that this limited evidence is not inappropriately interpreted to indicate a significant mortality risk from SCS.**

2. As previously stated in our January 11, 2010 comments to the HTA, the 2010 study by Turner et al. ("U of W study") contains a number of methodological limitations that substantially undermine its utility in assessing the clinical role of SCS. Further, its inclusion in your draft report as a source of evidence on key questions 1, 2 and portions of question 3 (with the exception of its reference to sub-populations at question 3.3) is inappropriate. The draft evidence report nevertheless gives substantial and undue weight to this prospective cohort (Level of Evidence III) study well beyond its limited focus on the workers' compensation sub-population. **We recommend that the evidence vendor limit its application of this evidence to its assessment of question 3.3 only and amend the summary evidence charts at pages 16, 17, 18 and elsewhere in the report (e.g., Table 11 at pages 124-127) to reflect this limited application of the U of W study.**

3. The draft evidence report does not include the technology assessment by researchers at Sheffield University in the United Kingdom, which was independently commissioned by the National Institute of Health & Clinical Excellence (NICE) in its evaluation of SCS for coverage by the National Health Service. **We recommend that the evidence vendor amend the report to include the entire Sheffield University technology assessment, noting its applicability to the key questions.**

4. The report presents an imbalanced and partial view of sponsorship of clinical studies. **We recommend that the HTCC evaluate the evidence based first and foremost on clinical design and relevant findings of the evidence.**

5. The report mischaracterizes the clinical role of SCS in treating chronic pain conditions, which further skews the analysis of the therapy. **We recommend that the evidence vendor amend the report at pages 7 and 22 to emphasize that the first goal of treatment for chronic pain conditions is to reduce the pain suffered by the patient.**

6. The evidence vendor inappropriately included clinical treatment guidelines that fall outside the scope of this assessment and did not include a relevant guideline by the American Society of Anesthesiologists (ASA). **We recommend that the evidence vendor include the ASA guidelines in its assessment of SCS and remove its reference to the North American Spine Society guidelines *Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (2007*), which refers to an off-label (not FDA approved) indication.**

We address each of these concerns in greater detail, below.

<u>Inaccurate/Misleading Presentation of Mortality Data</u>

Despite the absence of deaths attributable to SCS, it is troubling to note that extremely limited data are reported as having a "high" level of evidence in the summary chart of key question 2.3: *"What is the evidence of the safety of spinal cord stimulation – Mortality."* We

understand that this summary is intended to convey the strength of evidence, rather than an indication of the relative safety of SCS. However, this presentation could certainly lead some observers to conclude that SCS has a high incidence of mortality – a conclusion that is completely at odds with clinical practice and the long history of successful SCS implantations and long-term use by patients. At a minimum, this section implies that there is high-level evidence that clearly demonstrates a link between SCS and mortality, which is simply not accurate.

We urge the evidence vendor to amend the draft report, as noted above, and we urge the HTCC to properly evaluate SCS as a therapy with no therapy-induced deaths reported in the literature. By this measure alone, SCS has proven to be a remarkably safe therapeutic intervention when implanted by appropriately trained and experienced physicians.

Inappropriate Application of the University of Washington Study

As noted in the draft evidence report, the U of W study *"received the LoE grade of III."* (page 47). Enrollees in this prospective cohort study were limited to workers compensation claimants in the State of Washington. In our January 11, 2010 comments to the HTA, we noted several significant methodological limitations with this study and provided the HTA with extensive prior correspondence between NTAC and the study sponsor – the Washington State Department of Labor and Industries (L&I) – detailing our concerns. With this letter, we again provide copies of this correspondence and formally request that this information be included in the Health Technology Clinical Committee's review of evidence. These limitations clearly indicate that the generalizability of the U of W study is limited at best.

In summary, our concerns with the U of W study include the following:

- Non-randomized cohort groups: Absent randomization, there are no *a priori* selection criteria for each cohort group. As a result, essentially non-comparable groups of patients were nonetheless compared.

  This concern is reinforced by the draft evidence report: *"This (the U of W study) was a well conducted cohort study. However, the potential for selection bias is a threat to validity in any cohort study and is a limitation."* (page 74)

- The significant length of time that patients enrolled in the study were injured and receiving workers' compensation benefits (approximately 4 years in the case of SCS cohort participants) undermines the efficacy of any intervention. (Waddell, 1998; Waddell and Burton, 2001). It is well documented that this is an extremely difficult to treat population and any clinical study of a generally efficacious therapy could anticipate challenges meeting its primary endpoint in this patient group.

This concern is echoed in the draft evidence report: *"The mean duration of chronic pain was 38 months, and was significantly longer in the SCS group than in the PC group (P < .02)."* (page 73).

The study's composite outcomes measure is unprecedented in the literature on SCS and creates an inappropriate success threshold for SCS. On behalf of NTAC, Professor Rod Taylor (University of Exeter) analyzed the study's composite measure and concluded that, in addition to appearing nowhere in the published literature, it confounds the statistical assessment of the study's outcomes: *"Because of the way the authors have constructed the primary [outcome measure] (composite that requires that 3 separate outcomes be reached) means that it is a very rarely achieved outcome (e.g. 4% of SCS patients, 0% of PC and UC patients at 6 months). This rarity is particularly challenging. Take for example that 10% SCS vs. 5% of UC or PC patients achieved the primary outcome (i.e. a doubling of effectiveness), the study would require 474 per group to prove statistical significance. 0% vs. 4% (the actual results at 6 months) would require 239 per group." (unpublished correspondence)*

- A majority of patients treated with SCS in this study did not undergo a psychiatric evaluation to determine their eligibility for treatment as recommended by clinical practice guidelines and payer criteria such as the Medicare National Coverage Determination for SCS.

Again, we urge you and the HTCC to review our correspondence with L&I for a fuller discussion of these concerns.

Apart from the specific limitations in the study itself, however, we agree with the conclusion by the study authors in cautioning against its applicability beyond the workers' compensation program and in their acknowledgement that their reported outcomes may well be the result of confounding factors in the workers compensation population and system of care:

> *The lack of long-term effectiveness of SCS in this study does not necessarily imply ineffectiveness in other settings.* ***The issues associated with involvement in the workers' compensation system may be a stronger influence than pain therapy on patient outcomes.*** *It is possible that no treatment has a substantial impact on average in this patient group. An argument could be made for heightened scrutiny of all therapies applied in this population, especially those that involve substantial costs or risks, and for efforts to provide the most cost-effective care with the least possibility of harm. (Turner, et al., 2010)[1] [emphasis added]*

Given the clear methodological limitations of this study and the caution about its wider applicability by the authors themselves, we strongly question why this study has been

---

1 Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Turner Judith A; Hollingworth William; Comstock Bryan A; Deyo Richard A Pain 2010;148(1):14-25.

given significant prominence in the draft evidence report, not only with respect to questions regarding sub-population effects, but also in questions 1 and 2 (Efficacy/Effectiveness and Safety).

For example, in addressing key question 1, " *What is the evidence of efficacy and effectiveness of spinal cord stimulation,"* the evidence vendor included only the U of W study in its assessment of effectiveness (see summary of evidence table at page 15). Clearly, the evidence vendor has applied limited evidence from a small cohort of workers' compensation claims – to the exclusion of all other sources of evidence on clinical effectiveness – in assessing clinical effectiveness generally. It is concerning that a LoE III study enrolling a small number of workers compensation claimants in the State of Washington is presented as the exclusive source of evidence to address clinical effectiveness.

As noted above, even the study authors would seem to strongly caution against this application of their findings.

Therefore, we urge the evidence vendor and the HTCC to limit the applicability of this study to its evaluation of key question 3.3: *"What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations – 3rd party coverage?" (see, for example, summary of evidence on question 3.3 at page 17).*

In addressing clinical effectiveness for the workers compensation sub-population, we note that, despite a relatively modest outcome for all interventions in this study (i.e., SCS, CMM and Pain Clinic) – outcomes which are likely attributable to the overall poor outcomes within this population – there were notable secondary benefits reported by Turner et al. *"According to per-protocol analysis, patients who received SCS had significantly lower rates of surgery (other than SCS) at two years than those who underwent at least some Pain Clinic therapy (0% (0/27) versus 19% (4/21), P = .03)."* (page 76).

Based on this evidence of clinical effectiveness, SCS may well obviate the need for some costly surgical interventions and other pain care interventions within the workers compensation population.

<u>Omission of Tech Assessment by Sheffield University</u>

In the context of addressing key question 4 (*What is the evidence of cost effectiveness of spinal cord stimulation?)***,** the draft report refers to the unpublished technology produced by the School of Health and Related Research (ScHARR) at the University of Sheffield for the United Kingdom's National Institute of Health and Clinical Excellence (NICE) review of SCS (Simpson, 2009).

However, the authors of the evidence report neglect to include the full technology assessment in its review of SCS. In our January 11, 2010 comments to the HTA, we specifically requested that the full Sheffield technology assessment be included in the

vendor's review of evidence. If it was excluded because it is an unpublished document, the evidence vendor nevertheless included other unpublished documents in its review, including the 2008 NICE Final Appraisal Determination (FAD) on SCS. The Sheffield technology assessment is among the most comprehensive and independent assessments on the SCS available. Therefore, its absence in the draft evidence report is a significant omission that does not adequately account for a substantial body of work on this therapy.

We recommend that the evidence vendor amend the report to include the entire Sheffield University technology assessment, noting its applicability to each of the key questions.

Imbalanced Presentation of Potential Bias

The draft report states that industry-sponsored studies are more likely than others to produce results favorable to the sponsor. Such results, however, might simply be the result of a well-designed and well-executed study protocols. Further, sponsorship bias can influence study results in both directions, including sponsorship by payers – such as the Washington State Department of Labor and Industries – which may or may not have incentives that influence results. Bias can exist in any trial, regardless of the specific source of sponsorship. The ultimate goal is to acknowledge the potential and minimize its influence.

The authors of the evidence report appear to nominally acknowledge this two-way potential for bias in its description of the U of W study: *"While the study was not funded by a device manufacturer, it was commissioned by Washington State Department of Labor and Industries, which administers the workers'' compensation program."* (page 74**). We urge the HTCC to evaluate the evidence based on the quality of study design and not to pre-judge the evidence based on any *a priori* assertion of bias.**

Inaccurate Characterization of Pain Care

As a coalition of stakeholders focused on patient access to appropriate pain care, we are troubled by the characterization of pain care in the draft evidence report. Specifically, the report states that *"(t)he aim of treatment for chronic pain is to improve function and quality of life while relieving pain."* (page 7 and 22).

In fact, the first aim of pain care is to relieve the pain experienced by the individual living with this debilitating condition. Once the pain is appropriately controlled or alleviated to the greatest extent possible, it is clearly the goal of treatment to improve overall function and quality of life. This distinction is critical. If we lose sight of the immediate goal of controlling pain, it is often an easy step to assert that the goal of pain care is, for example, to return individuals to work. While improvements in function and quality of life are clearly important, placing the primary emphasis on these goals often introduces factors beyond the control of the clinician and the even the individual living with pain as the measure of clinical success.

Whether the intervention is aspirin or SCS, the first objective is to alleviate the pain and suffering of the individual living with this condition. **Therefore, we recommend that the evidence vendor amend the report at pages 7 and 22 to emphasize that the first goal of treatment for chronic pain conditions is to reduce the pain suffered by the patient.**

Inaccuracies in Section 2.5

The evidence vendor included in its compilation of guidelines the following: *North American Spine Society (NASS): Diagnosis and treatment of degenerative lumbar spinal stenosis (2007).* We note that these guidelines refer to off-label (not FDA approved) indications for SCS, which we believe fall outside the scope of this review. **Therefore, we urge the evidence vendor to strike these guidelines from consideration and we urge the HTCC to not weight these guidelines in its assessment of SCS for FBSS and CRPS.**

This section also omits an important updated set of guidelines on chronic pain, recently published by the American Society of Anesthesiologists (ASA).[2] These guidelines contain specific language on SCS as a therapeutic option. We understand that the evidence vendor may have missed these guidelines due to the timing of publication. **Nevertheless, given the recent publication of the guidelines from one of the leading national societies in the field of pain medicine, we recommend that the evidence vendor include the ASA guidelines in its assessment of SCS.**

Thank you for the opportunity to provide these comments and for your full consideration in this process. Please do not hesitate to contact me with any questions.

Sincerely,

Eric Hauth, Executive Director
eric@neuromodulationaccess.org

cc: Leah Hole-Curry, Program Director
Spectrum Research
Joshua Prager, MD – NTAC Chair
David Kloth, MD – NTAC Vice Chair

[2] **Practice Guidelines for Chronic Pain Management -** An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine*Anesthesiology 2010; 112:1–1

Ensuring Patient Access. Promoting Quality Care.
www.neuromodulationaccess.org

February 28, 2008

Judy Schurke, Director
Department of Labor and Industries
Post Office Box 44100
Olympia, Washington 98504

Re: *Spinal cord stimulators (SCS) for injured workers with chronic low back and leg pain after lumbar surgery – A prospective study to describe costs, complications, and patient outcomes.* Hollingworth W, Turner J, Comstock BA, Deyo R. 30th April 2007.

Dear Ms. Schurke:

On behalf of the Washington Society of Interventional Pain Physicians (WSIPP) and the Neuromodulation Therapy Access Coalition (NTAC), a newly formed 501c(4) coalition, we are writing regarding the above-referenced study on the use of spinal cord stimulators (SCS), commissioned by the Washington State Department of Labor and Industries (L&I). We wish to request a meeting with you, your staff and selected representatives of our organizations, to introduce you to WSIPP (a chapter of the American Society of Interventional Pain Physicians or ASIPP) and NTAC. Specifically, we would appreciate an opportunity to discuss the preliminary draft of this study, the broader context of evidence, and the national standard of care on spinal cord stimulators so that we can work collaboratively to ensure appropriate patient access to needed therapies as you move forward with possible coverage decisions.

For your reference, the membership in NTAC (www.neuromodulationaccess.org) includes multiple physician societies and medical device manufacturers dedicated to ensuring appropriate access to neuromodulation devices, including Spinal Cord Stimulation, which is a vitally important therapy used to treat certain forms of chronic, debilitating pain.

We support the appropriate use of evidence-based medicine to inform reasonable coverage policies that also respect the standard of care and opinions of experts. This approach would be in keeping with the Washington Administrative Code (WAC). Our review of the preliminary study report highlights the importance of both evidence-based medicine and critically understanding the strengths and weaknesses of any given study. We fully understand that there is no perfect study. However, it is critical that this study and any evidence be viewed in the larger context of available evidence, before being used as the basis for possible coverage decisions.

Thank you in advance for your assistance in facilitating a meeting of interested stakeholders to discuss this study. We look forward to introducing you to our organizations and working with you to develop the best possible approaches in the evaluation and coverage of neuromodulation therapies. Should you have questions or comments, please contact Eric Hauth, NTAC Executive Director, at eric@neuromodulationaccess.org or (651) 278-4238. Mr. Hauth will work with your office to coordinate a future meeting.

Sincerely,

Joshua Prager, MD – Chair
NTAC

Joseph Jasper, MD – CEO
WSIPP

Arthur Watanabe, MD – President
WSIPP

Andrea Trescot, MD – President
ASIPP

May 30, 2008

Judy Schurke, Director
Department of Labor and Industries
Post Office Box 44100
Olympia, Washington 98504

Re: Washington State DLI Study *Spinal cord stimulators (SCS) for injured workers with chronic low back and leg pain after lumbar surgery – A prospective study to describe costs, complications, and patient outcomes.* Hollingworth W, Turner J, Comstock BA, Deyo R. 30th April 2007.

Dear Director Schurke:

On behalf of the Neuromodulation Therapy Access Coalition (NTAC), I want to extend my thanks to you and your staff for taking the time to meet and discuss the above referenced draft study by Hollingworth, et al. on May 5. We also appreciate the opportunity to highlight published evidence on spinal cord stimulation (SCS), including randomized controlled trials (RCTs) in support of SCS, as well as the Reden & Anders actuarial analysis that demonstrates the cost savings the Department would experience in appropriately covering this important therapy.

As we noted in the meeting, there are a number of methodological concerns with this study, which significantly limit its ability to meaningfully inform the discussion on the efficacy of SCS for properly selected patients. While we understand that the preliminary report we reviewed does not reflect the final results of the 24-month study, the underlying methodological concerns generally cannot be resolved "mid-stream." These concerns include problems with overall design, patient selection, screening trials for SCS, data collection, definition of success, the vast majority of which are unfortunately impossible to address at this late date. Despite these serious methodological flaws, it is noteworthy that the "sub-group as-treated analysis," which most fairly portrays the reality of this therapy, actually suggests a positive SCS outcome in support of reasonable coverage.

Overall, we wish to emphasize three fundamental issues for your further consideration:

1. **As-treated Results Are Positive for SCS:** The Hollingworth study demonstrates that patients who received full implantation of a spinal cord stimulation system (11/24 or 46%) demonstrated substantial improvement in overall function. It must be emphasized that this success rate was achieved even with the methodological problems noted above. We urge the Department not to lose sight of this important information.

2. **Cost-effectiveness for SCS Clearly Demonstrated by Actuarial Analysis:** Real-world United Health Group (UHG) claims data and the expert actuarial analysis provided by Reden & Anders, a subsidiary of UHG, demonstrate that SCS is cost-effective for payers, reducing utilization of other healthcare services and related claims costs for properly selected patients. Importantly, this actuarial analysis further validates other cost-effectiveness data available on SCS. In any event, it is clear that the therapy is either superior or equal to other treatments, and that its use causes a reduction in other health care services and related costs for properly selected patients.

3. **Return-to-Work (RTW) Not a Valid Therapeutic Indicator this Late in the Treatment Ladder:** As we discussed, this study looks only to those who have been off work for a long duration. As published data support, these injured workers are simply not likely to return to work, regardless of the treatment. No therapy can be fairly evaluated on the basis of this late-stage return-to-work, given the dependency of return-to-work on factors beyond the control of either the patient or the intervention. Further, while clearly return-to-work remains an admirable goal, the reality is that there will be patients who do not return-to-work, but who were injured on the job and with appropriate medical care can experience significant pain relief and improved function. If understood in that reasonable framework, SCS is a therapy that continues to provide meaningful relief and improved function for thousands of Americans covered under Medicare, Medicaid, private insurance, DOD VA and all other workers' compensation programs in the country. We believe Washington injured workers deserve no less.

Given its potential long-term implications for injured workers' access to SCS in Washington State, we invite a continuation of this dialogue. Specifically, we would ask your consideration of the following:

Independent Critique of the Hollingsworth Study is Necessary. As is typical in the development of clinical studies, we urge the Department to seek an objective, authoritative peer review of the completed study prior to any publication. We believe that such review will further confirm the concerns we have raised. Regardless, it must be emphasized that the study and its design, particularly when viewed in isolation from the vast body of equal-to or higher levels of evidence that also supports reasonable evidence-based coverage, would seem to contradict the vast body of supportive literature and positive coverage decisions from carriers and governments throughout the country.

We respectfully encourage the Department and the State to join the vast majority of private and public payors in the country and provide injured workers ongoing, appropriate coverage for spinal cord stimulation. SCS is a covered benefit under Medicare and other governmental health care programs, all major commercial health plans, and most Workers' Compensation programs in the U.S. The Centers for Medicare and Medicaid Services (CMS) provided national coverage for SCS after determining that the therapy met the agency's stringent requirements for medical necessity. Most major private payers including Aetna, Cigna, United Healthcare, Blue Cross/Blue Shield, and Health Net, and local plans including Regence and Primera, have formal, reasonable coverage policies for SCS, with Group Health of Puget Sound covering SCS on a case-by-case basis. The US Military Health System also covers SCS for active and retired

military personnel and their families. We believe Washington State injured workers deserve no less.

We would invite further discussion about the development of a draft coverage policy for the Department of Labor and Industries and stand ready to assist in drafting of this policy. Apart from the draft study by Hollingworth, et al., as mentioned above there is substantial published literature demonstrating both clinical and cost effectiveness of SCS for failed back syndrome and chronic neuropathic pain, and a great deal of local and national interventional pain medical expertise on which to rely. We offer the attached bibliography of supporting literature for your reference.

Thank you again for your time and attention to this matter. We hope that the Department and the study team will take these comments into consideration as the study is completed and any final report issued, and as the Department considers appropriate next steps. We also look forward to working with you and your staff to ensure that injured workers in Washington get the therapy options they need to manage their chronic pain and live the most productive lives possible.

Sincerely,

Eric Hauth, Executive Director
Neuromodulation Therapy Access Coalition

Cc: Joshua Prager, MD – NTAC Board Chair
Richard North, MD – The Neuromodulation Foundation

Appendix – Supporting Literature

Randomized Controlled Trials

Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial.J Neurosurg. 2008 Feb;108(2):292-8.

Kemler MA, DeVet HC, Barendse GA, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol 2004;55:13-8.

Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 2000;343:618–24.

Kumar K, Taylor RS, Jacques L, Eldabe S, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179-188.

North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005;56:98-106; discussion 106-7.

North RB, Kidd DH, Lee MS. Spinal cord stimulation versus operation for failed back surgery syndrome: a prospective, randomized controlled trial. Acta Neurochir Suppl 1995;64:106-8.

North RB, Kidd DH, Lee MS. A prospective randomized study of spinal cord stimulation versus reoperation for failed back surgery syndrome: initial results. Stereotact Funct Neurosurg 1994;62:267-72.

Tesfaye S, Watt J, et al., Electrical spinal-cord stimulation for painful peripheral neuropathy. Lancet. 1996;348:1698-701.

Long-Term Outcomes Studies

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurg. 2006;58:481-496.

Kumar K, Nath R, Wyant GM. Treatment of chronic pain by epidural spinal cord stimulation: a 10-year experience. J Neurosurgery 1991;75(3):402-7.

North RB, Kidd DH, Zahurak M, et al. Spinal cord stimulation for chronic, intractable pain: experience over two decades. Neurosurgery 1993;32(3):384-94; discussion 394-95.

North RB, Ewend MG, Lawton MT, et al. Failed back surgery syndrome: 5-year follow-up after spinal cord stimulator implantation. Neurosurgery 1991;28(5):692-99.

Practice Guidelines and Position Statements

American Society of Anesthesiologists Task Force on Pain management. Practice guidelines for chronic pain management. A report from the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section.Anesthesiology. 1997 Apr;86(4):995-1004.

Boswell MV, Shah RV, Everett CR, et al. (American Society of Interventional Pain Physicians). Interventional techniques in the management of chronic spinal pain: evidence-based practice guidelines. Pain Physician. 2005;8:1-47.

Cruccu G, Aziz TZ, Garcia-Larrea L, et al. EFNS guidelines on neurostimulation therapy for neuropathic pain. Eur J Neurol. 2007 Sep;14(9):952-70.

North R, Shipley J, Prager J, et al..Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain.Pain Med. 2007 Dec;8 Suppl 4:S200-75.

Stanton-Hicks M, Burton AW, Bruehl SP, et al. An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. Pain Practice 2002;2:1–16.

Cost Effectiveness

Hornberger J, Kumar K, Verhulst E, et al. Rechargeable spinal cord stimulation versus nonrechargeable system for patients with failed back surgery syndrome: a cost-consequences analysis. Clin J Pain. 2008;24:244-252.

Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. Neurology 2002;59:1203–09.

Manca A, Kumar K, Taylor RS, et al. A multicentre randomised controlled trial comparing spinal cord stimulation with conventional medical management for neuropathic pain in patients with failed back surgery syndrome (PROCESS trial): quality of life, resource consumption and costs. Eur J Pain, in press, 2008.

North RB, Kidd D, Shipley J, Taylor R. Spinal cord stimulation versus reoperation for failed back surgery syndrome: A cost effectiveness and cost utility analysis based on a randomized, controlled trial. Neurosurgery 61(2):361-369, 2007.

Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: A decision analytic model and cost effectiveness analysis. Int J Technol Assess Health Care 21:351-355, 2005.

Taylor RS, Taylor RJ, Van Buyten J-P, et al. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. J Pain Sympt Manage 27(4):370-378, 2004.

File:
WA > WC > SCS

STATE OF WASHINGTON

DEPARTMENT OF LABOR AND INDUSTRIES

PO Box 44000 • Olympia, Washington 98504-4000

June 27, 2008

Eric Hauth, Executive Director
Neuromodulation Therapy Access Coalition
855 Village Center Drive, #363
North Oaks, MN 55127

N. William Fehrenbach
Medtronic Neurological
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604

Dear Mr. Hauth and Mr. Fehrenbach:

Thank you for you letter of May 30, 2008, outlining your concerns about the Department's Spinal Cord Stimulator (SCS) Study. As we agreed, the specific methodologic concerns you raised in our May 5th meeting were forwarded to the investigators at the University of Washington.

As you know, the department funded this study to develop real-world (effectiveness research) evidence of the safety, effectiveness and cost of SCS when used in an injured worker population in Washington State. The researchers who designed the SCS study protocol include very experienced and highly regarded University of Washington professors. I have complete confidence that the work this group is performing is to high standards and will result in a highly credible report including appropriate discussion of the strengths and limitations of the study.

In our meeting on May 5th Medtronic offered $25,000 for an independent review of the study design. The department respectfully declines this offer, as we do not accept money from outside sources to develop information for purposes of public policy.

In designing the study, a randomized controlled trial (RCT) design was considered, but was determined to be impractical. This was due in part to the prohibitively high cost of such an RCT. As you point out, the evidence generated by this non-randomized controlled study will not be the same as that provided by a well-designed RCT, but it will provide unique evidence of the real-world effects, safety and costs of SCS specific to individuals receiving workers' compensation benefits when treated by their own community physicians. To date, there is no substantial evidence available on the effectiveness of SCS technology in this population.

Any change to SCS coverage policy will include consideration by the Industrial Insurance Medical Advisory Committee, through an open and public process. Results from the SCS study will be vetted by this committee, as well as by a medical journal review process should the researchers pursue publication. Consideration by the Industrial Insurance Medical Advisory Committee will provide opportunities for open and public review of the study strengths, limitations and findings.

I anticipate receiving the final report from the University of Washington in early October 2008. At that time we will initiate a review of the current SCS coverage policy.

Sincerely,

Judy Schurke
Director

cc: Bob Malooly, Assistant Director
for Insurance Services
Gary Franklin, MD, Medical Director
Vickie Kennedy, Special Assistant to the Director

NTAC

neuromodulationaccess.org

Ensuring Patient Access. Promoting Quality Care.

October 14, 2008

Judy Schurke, Director
Department of Labor and Industries
Post Office Box 44100
Olympia, Washington 98504

Re: Washington State DLI Study *Spinal cord stimulators (SCS) for injured workers with chronic low back and leg pain after lumbar surgery – A prospective study to describe costs, complications, and patient outcomes.* Hollingworth W, Turner J, Comstock BA, Deyo R. September, 2008.

Dear Director Schurke:

On behalf of the Neuromodulation Therapy Access Coalition (NTAC), I want to thank you for the continued, open dialogue concerning the above-referenced study. As this study has now been completed, and one of the authors is scheduled to present the findings this week at the October 16, 2008 meeting of the Industrial Insurance Medical Advisory Committee (IIMAC) meeting, we want to again note some significant concerns with the study and its conclusions. We stress that this study and its results stand in stark contrast to the vast body of published literature on SCS, as well as a recent technology review completed by the United Kingdom's National Institute for Clinical Effectiveness (NICE), the widely respected European health technology assessment program.

We also request that this letter be shared with the IIMAC chair and committee members prior to the October 16 meeting in order to provide a fuller context for the discussion. Finally, while we understand that the meeting on October 16 does not provide an opportunity for public comment, we would like to formally request time at any subsequent discussion of this study by the IIMAC, allowing for direct input to the committee by experts in this important therapy. Please note NTAC has recently contracted with the Delfini Group, based in Washington State, to conduct an independent evidence-based review of the study, and we look forward to including the results of that review in our subsequent discussions.

We have reviewed the final study report and, while there are some changes from the draft report, the final report is largely unchanged. As noted in our May 30 letter, there are a number of methodological concerns with this study, which significantly limit its ability to meaningfully inform the discussion on the efficacy of SCS for properly selected patients. These concerns include problems with the overall study design, patient selection, screening trials for SCS, data collection, and definition of success, the vast majority of which were unfortunately not addressed in the final report. Overall, we wish to emphasize the following issues for your agency's further consideration:

1. **Study design results in poor quality evidence**
   - Validity concerns due to non-randomization.

2. **Workers' Compensation patients**
   - Participants sustained injury on average 4 years prior to enrollment;
   - Regardless of intervention, such participants are very unlikely to return to work; and
   - Participants may have a disincentive (loss of benefits) to report successful treatment.

3. **Selection bias likely**
   - It is unclear how patients were funneled to any of the three treatment groups; and
   - Most SCS patients agreed to participate, whereas less than 50% of the patients in other two groups could be contacted and agreed to participate.

4. **Analyses: None presented are ideal**
   - Intention-to-treat (ITT) analysis is not appropriate, whereas as-treated analysis was not done;
   - Over 50% of SCS group did not receive intervention; and
   - Permanently implanted patients showed both an improvement in pain and disability.

5. **Several studies demonstrate that SCS is cost-effective**
   - Actuarial analysis from the United HealthCare (UHC) claims data noted in our previous discussion on this study, modeled data based on published literature, and data collected from prospective uncontrolled studies as well as a randomized control trial support the cost argument for SCS over other treatments (e.g. CMM, PT, reoperation); and
   - The UK's National Institute for Clinical Effectiveness (NICE) just released a new Final Appraisal Determination (FAD) recommending coverage for SCS throughout the entire UK National Health Service for failed back surgery syndrome (FBSS) and chronic regional pain syndrome.

Importantly, NICE issued its finding subsequent to our meeting in May. They state (and we agree) that "SCS is not suitable for everyone with chronic pain, and that it should be used only as part of a multidisciplinary team approach with other therapies and a strategy for rehabilitation."

With this appropriate caveat, however, NICE definitively concluded in its review of the literature that SCS for failed back surgery syndrome and CRPS is both clinically and cost effective. They state further "that, for FBSS and CRPS, the evidence suggested that SCS was more effective reducing pain than CMM," and the they found that "SCS for the treatment of FBSS and CRPS would be a cost-effective use of NHS resources."

Contrary to the conclusions in the study by Hollingworth, et al., the NICE committee evaluating SCS "was persuaded that, on balance, if people with severe pain of neuropathic origin were appropriately identified, that is, undergo an assessment by a specialist multidisciplinary team which included a successful trial of stimulation, then the evidence of benefit could be generalized. The Committee therefore concluded that the use of SCS should be recommended as a treatment option for all chronic pain conditions of neuropathic origin."

Unfortunately, it would appear that these conditions were not met in the Hollingworth et al. study, which – by design – not surprisingly resulted in minimal impact of SCS in the treatment of the study participants' neuropathic pain.

We strongly urge your department and the IIMAC to view the University of Washington in the broader context of literature on SCS and, in particular, the conclusions reached by NICE in its evaluations of this therapy for individuals with chronic, neuropathic pain.

We look forward to continued dialogue on this important issue and addressing any questions you and the IIMAC may have.

Sincerely,

Eric Hauth, Executive Director
eric@neuromodulationaccess.org
(651) 278-4238

NTAC

neuromodulationaccess.org

Ensuring Patient Access. Promoting Quality Care.

February 6, 2009

Judy Schurke, Director
Department of Labor and Industries
Post Office Box 44100
Olympia, Washington 98504
Via email: scju235@lni.wa.gov

Dear Judy:

Thank you for taking the time on January 23 to again discuss the extremely important issue of access by injured workers in Washington State to spinal cord stimulation (SCS) for the treatment of chronic, neuropathic pain. We appreciate the open dialogue and continue to strongly encourage your re-consideration of Labor and Industries' (L&I) non-coverage policy.

To that end, it is important to re-cap several facts about spinal cord stimulation (SCS) and conclusions concerning the University of Washington study (Hollingworth, Turner, et al.)

1. Multiple randomized controlled trials have demonstrated that SCS is a clinically effective treatment option for chronic neuropathic pain. Therefore, L&I's evidence ranking criteria should incorporate results of these well-designed clinical studies.

2. Washington L&I's non-coverage policy of SCS for Workers' Compensation patients is inconsistent with coverage policies of Medicare and every other Workers' Compensation program in the United States. SCS is widely covered in the general population, both in the United States and in many countries throughout the world – as well as all other state workers' compensation programs in the United States.

3. Contrary to the assertion that SCS proved ineffective in the University of Washington study, it actually showed good results, when the denominator reflects those patients actually receiving the therapy.

Despite these facts, they appear to have had little bearing on the decision by L&I to affirm its existing non-coverage policy.

In our meeting on January 23, for example, Dr. Franklin stated that the sub-population study by the University of Washington (Hollingworth, Turner, et al.) carries a higher weight than, for example, randomized controlled trial evidence for SCS[1] [2] [3] and the positive evidence-based

[1] Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008 Oct;63(4):762-70.

technology appraisal for SCS for chronic neuropathic pain that was conducted by the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom.[4]

However, we see nothing in L&I's own evidence ranking criteria that would justify disregarding well-designed, high-quality studies from the general population. This approach is unsupported by L&I's governing regulations concerning evidence reviews.

Second, in our meetings with you and your staff and the Industrial Insurance Medical Advisory Committee (IIMAC), we heard on several occasions that "workers' compensation patients are different," i.e., outcomes for various treatments are generally lower among this population than outcomes for similarly injured, non-workers' compensation patients.

If one assumes that "workers' compensation patients are different" -- a sentiment that is beyond the scope of the UW study or the agency's coverage policies -- one must conclude that this difference is due to (a) the incentive structure in workers compensation programs that would lead to under-reporting of therapeutic results in order to maintain disability benefits; or (b) the presumption that workers' compensation patients fare worse clinically than similarly injured patients in the general population.

Therefore, either patients in the UW study experienced *better* results from SCS than reported or there exist other, confounding variables in their care that limit the effectiveness of treatment. Neither explanation supports the conclusion that SCS failed to work.

As Professor Taylor noted, for example, patients enrolled in the UW study were out of work and injured far longer than is typical in studies evaluating this therapy for the general population. We note that these explanations demonstrate that SCS is either *more* – not less – effective than reported or that the level of disability sustained by the patients in the study makes it unlikely that *any* therapeutic intervention would overwhelmingly prove effective.

Third, L&I has concluded that the results of the UW Study demonstrate that SCS is not rehabilitative – a conclusion with which we strongly disagree and one that fails to account for improvements in quality of life for patients with neuropathic pain. We also note that this conclusion was communicated in a December 2, 2008 letter to physicians throughout the state in advance of IIMAC's vote on the narrow question posed by L&I: "Does the Turner et al. study from the University of Washington provide evidence to change the Department's existing non-coverage policy for Spinal Cord Stimulator Devices?"

---

[2] Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain. 2007 Nov;132(1-2):179-88.

[3] North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery. 2005;56(1):98-106.

[4] Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE Technology Assessment Appraisal 159. Online: www.nice.org.uk/Guidance/TA159/Guidance/pdf/English.

However, when properly analyzed, the outcomes from the UW study (i.e., patients reporting statistically significant reduction in baseline pain) are actually comparable to results found in other, peer-reviewed studies for the general population. Contrary to the assertion that SCS proved ineffective, it showed good results when the denominator reflects those patients actually receiving the therapy. As the chart, below, indicates:

- Even if one uses the more conservative intention to treat analysis (ITT), in which the denominator reflects the entire study arm whether or not someone actually received a stimulator implant, SCS is more than three times as effective as treatment in the pain clinic (18 percent vs. 5 percent of patients achieving benchmark outcomes).

- Applying the more appropriate per RX or "as treated" analysis, in which the denominator reflects those patients actually receiving the implant, the results are even more pronounced (33 percent vs. 9 percent achieving benchmark outcomes). This approach reflects real-world practice, in which patients are first given trial stimulation to determine whether or not they are appropriate candidates for this therapy.

- The pain clinic and usual care groups showed far less improvement in pain reduction or function, clearly indicating just how unresponsive this group of study participants was to treatment. Despite this fact, those receiving SCS did remarkably well.

UW Study Patient Outcomes (assuming "As Treated" Measure)

	SCS	**Pain clinic**	**Usual care**	**P-value**
ITT	9/51 (18%)	2/39 (5%)	2/68 (3%)	0.09 0.02
Per Rx	9/27 (33%)	2/23 (9%)	2/68 (3%)	0.04* 0.0001*

* Calculated by Professor Taylor - Fisher's Exact p

We believe a fair review consistent with the agency's evidence ranking criteria would likely rank the referenced RCTs and the NICE determination "A" or "B" level evidence and the UW study "C" level evidence. Such a review would appropriately support a positive coverage determination for this therapy. In addition, were the reference studies "C" level evidence, it seems likely that L&I would discount their relevancy based on this evidence ranking. We fail to understand how a lower-rated study used to deny coverage trumps higher-level RCTs in favor of a therapy. Regardless, nothing in L&I's criteria provides for this two-tier evidence ranking based on sub-population weighting.

Based on these important considerations, we again strongly recommend that L&I re-consider its determination and implement a coverage policy comparable to the UK's NICE recommendation, pending possible future evaluation of this therapy by the state's Health Technology Assessment (HTA) program. The NICE recommendation states clearly:

> ***"Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who:***
>
> - ***continue to experience chronic pain (measuring at least 50 mm on a 0-100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and***
>
> - ***who have had a successful trial of stimulation as part of the assessment specified in recommendation.***
>
> ***Spinal cord stimulation should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed."***

We stand ready to assist your agency to fully assess the current peer-reviewed evidence on SCS and implement an appropriate coverage decision for this important therapy, pending possible future review by HTA. However, we also strongly believe that L&I's current non-coverage of SCS as a treatment option fails to meet the needs of injured workers with neuropathic pain and is not supported by the agency's evidence-ranking criteria.

Sincerely,

Eric Hauth, Executive Director
eric@neuromodulationaccess.org
(651) 278-4238
cc: Joshua Prager, MD – NTAC Chair

NTAC Membership:
American Academy of Pain Medicine
American Pain Foundation
American Society of Interventional Pain Physicians
Boston Scientific Neuromodulation
International Spine Intervention Society
Johnson & Johnson/DePuy
Medtronic Neuromodulation
National Pain Foundation
North American Neuromodulation Society
St. Jude Medical Neuromodulation

STATE OF WASHINGTON
DEPARTMENT OF LABOR AND INDUSTRIES
PO Box 44000 • Olympia, Washington 98504-4000

March 4, 2009

Eric Hauth, Executive Director
Neuromodulation Therapy Access Coalition
1313 Karth Lake Circle
Arden Hills, MN 55112

Dear Mr. Hauth:

Thank you for your February 6, 2009, letter regarding the department's Spinal Cord Stimulator policy and for our meeting on January 23, 2009.

As you know, the University of Washington (UW) study of SCS was carried out to develop workers' compensation specific evidence on this treatment among a Washington State sample of injured workers. The study was designed and completed by independent researchers who are highly experienced in many areas of clinical research, including those related to chronic pain. I have great confidence in and respect for the integrity of these researchers and for the quality of their work. The pragmatic design allowed for a well-powered study of the real-world outcomes of SCS treatment when prescribed, trialed, and permanently implanted by community physicians.

The UW study findings, with regard to effectiveness, are in contrast to the efficacy data from the small number of previously published studies addressing failed back surgery syndrome. Remarkably consistent adverse event rate findings emerged compared with available studies. However, the unique attributes of the UW study provide much needed and scientifically valid information to address the public policy question of whether SCS should be a covered benefit for injured workers in Washington. Key features of the study making it most relevant to this question include:

- All participants are from a workers' compensation population
- All care was directed by the patients' community doctors
- SCS devices were not brand specific
- All cost data, for SCS and comparative treatment, were captured in real-time

We have concluded, with advice from the Industrial Insurance Medical Advisory Committee, that SCS for injured workers with FBSS is not an effective treatment as measured by improvement in pain and function, using the criteria and methods currently in practice among community doctors. The study confirmed high rates of adverse events, sometimes serious and life threatening. The study also showed a high rate of removal for permanently implanted stimulators, though all workers were screened using trial stimulation.

As you know, the assessment of the strengths and weaknesses of scientific studies in other populations will proceed when the State Health Technology Program prioritizes this technology for review. Before then, we will be happy to review and give strong consideration to any new, high-quality peer-reviewed literature that becomes available and adds to our understanding of when to use this treatment for chronic pain in this population.

Sincerely,

Judy Schurke
Director

cc: Bob Malooly, Assistant Director
for Insurance Services
Gary Franklin, Medical Director

NTAC

neuromodulationaccess.org

Ensuring Patient Access. Promoting Quality Care.

April 10, 2009

Judy Schurke, Director
Department of Labor and Industries
Post Office Box 44100
Olympia, Washington 98504

Dear Director Schurke:

Thank you for your March 4, 2009 letter in response to our February 6, 2009 letter regarding the Department of Labor and Industries' (L&I) non-coverage policy for spinal cord stimulation (SCS) for injured workers with chronic, neuropathic pain.

For the record, we continue to have significant concerns with the department's interpretation of the University of Washington study and continuation of the SCS non-coverage policy; the discounting of other, published evidence, contrary to the stated requirements of the Washington Administrative Code (WAC); and several statements made in the department's latest response, which are not supported by facts.

Further, we are concerned that your March 4, 2009 letter did not address a number of specific concerns that we raised in our meeting with you and your staff and re-stated in our follow-up correspondence.

In response to your latest letter, we note the following:

First, your response states that the University of Washington study was "well powered." In an analysis of the results, Professor Rod Taylor (University of Exeter), whom you met at our January 23, 2009 meeting, states the following:

> *"Because of the way the authors have constructed the primary [outcome measure] (composite that requires that 3 separate outcomes be reached) means that it is a very rarely achieved outcome (e.g. 4% of SCS patients, 0% of PC and UC patients at 6 months). This rarity is particularly challenging. Take for example that 10% SCS vs. 5% of UC or PC patients achieved the primary outcome (i.e. a doubling of effectiveness), the study would require 474 per group to prove statistical significance. 0% vs. 4% (the actual results at 6 months) would require 239 per group."*

Therefore, the study design simply does not support the statement that it was statistically "well powered." Rather, the study was substantially underpowered to detect a statistically and clinically significant difference in the primary outcome measure.

Second, your response states that the University of Washington study provides "real world outcomes." However, Professor Taylor and previously Dr. Richard North – both of whom are

world-renowned experts on SCS – have confirmed that the composite outcomes measure appears nowhere else in the literature on SCS.

Further, it is extremely important to note again that SCS significantly outperformed both the pain clinic and usual care despite the various limitations in the study that we have described, including the length of time that participants were injured – a factor that greatly limits the potential effectiveness of any treatment intervention. It is unclear why the department continues to maintain that SCS did not achieve positive real-world outcomes when it clearly outperformed both the pain clinic and usual care groups.

Again, we present these results in the chart, below:

UW Study Patient Outcomes (assuming "As Treated" Measure)

	SCS	**Pain clinic**	**Usual care**	**P-value**
ITT	9/51 (18%)	2/39 (5%)	2/68 (3%)	0.09[1] 0.02[2]
Per Rx	9/27 (33%)	2/23 (9%)	2/68 (3%)	0.04[1,3] 0.0001[2,3]

1 – SCS vs. Pain Clinic
2 – SCS vs. Usual Care
3 – Calculated by Professor Taylor - Fisher's Exact Test

Third, your response letter states that the results of the University of Washington study "are in contrast to the efficacy data" found in other, published studies on SCS. We completely agree that this contrast exists, but note again that this discrepancy is due to the limitations in the University of Washington study, which is a non-randomized study involving substantially different cohorts.

Further, as we noted in our previous letter, we question why the department continues to discount the relevant peer-reviewed, published evidence on SCS – such as the PROCESS randomized controlled trial – which provides a much higher level of evidence from an evidence-based medicine perspective than the University of Washington study.

Under WAC 296-20-02704 (2)(b), the department is required to give "the greatest weight … to the most rigorously designed studies and … those well-designed studies that are reproducible." (Emphasis added). The reference studies in contrast to the University of Washington study are more rigorously designed and far more reproducible. Nonetheless, the department continues to ignore this important regulatory requirement.

Fourth, the department states that the University of Washington study resulted in "remarkably consistent adverse events." This statement is actually refuted by the authors of the University of Washington study. According to the study authors, *"a systematic review of the studies evaluating adverse events associated with SCS implantation…found a median superficial infection of 4%, lower than the 11% rate in our study. Among the studies reviewed, the mean rate of persistent pain in our region of the stimulator components was 5.8% (median 0), also lower than in our study."*

The relatively high-rate of complications in the University of Washington study is, in fact, inconsistent with rates of complications found in the most rigorous published evidence on SCS, suggesting a further limitation in the University of Washington study.

Fifth, the department states that one of the "key features" of the University of Washington study is that "all participants are from the workers' compensation population." As we noted in our previous letter, we can find nothing in the administrative rules governing L&I's review of evidence that provides for this sub-population ranking of evidence. We therefore question the legal and regulatory basis for this highly unusual approach to evidence review.

Finally, the department states "SCS for injured workers with FBSS (failed back surgery syndrome) is not an effective treatment measured by improvement in pain and function, using the criteria and methods currently in practice among community doctors."

The department asserts this viewpoint even though it is contradicted by the clinical experience of relevant professional societies and thousands of physicians and patients throughout the country, multiple positive randomized controlled trials, a longstanding positive National Coverage Decision by Medicare, a positive determination by the UK's National Institute of Health and Clinical Excellence, coverage by the DOD/VA and TriCare, coverage of SCS by all other state workers' compensation programs in the United States and coverage of SCS by virtually every major private payer.

Although the department offers to "review and give strong consideration to any new, high-quality, peer-reviewed literature that becomes available," we again question why the department has substantially disregarded recent randomized trials contrary to the rules governing L&I's decisions.

Again, we stand ready to assist the department in developing an appropriate coverage policy that is fully reflective of the published evidence; consistent with Medicare, private payers and other state workers' compensation programs; and based on clinically relevant patient selection and outcomes criteria.

Sincerely,

Eric Hauth, Executive Director
eric@neuromodulationaccess.org / (651) 278-4238

STATE OF WASHINGTON
DEPARTMENT OF LABOR AND INDUSTRIES
PO Box 44000 • Olympia, Washington 98504-4000

July 24, 2009

Eric Hauth, Executive Director
Neuromodulation Therapy Access Coalition
1313 Karth Lake Circle
Arden Hills, MN 55112

Dear Mr. Hauth:

I am writing in reply to your April 10, 2009, letter regarding the non-coverage policy for spinal cord stimulation (SCS) for injured workers in Washington State. I reviewed your letter with department clinical, research, and legal staff in order to fully understand your concerns about the University of Washington study of SCS (UW Study).

This research measured and reported the outcomes of injured workers in Washington State after at least 12 months of treatment. All treatment decisions were made by the injured workers and their physicians. The UW Study provides information on the comparative effectiveness of SCS, usual care and pain clinics as they were requested in our state during the time period of the study. The observational design and the conduct of the study are recognized as an important way to compare different medical treatments in the US as we face ever increasing healthcare costs. Dr. Turner was recently an invited speaker on this work at the Agency for Healthcare Research and Quality's *Comparative Effectiveness Research Methods Symposium* in June 2009.

As you know, the authors have reported the key outcomes and the methods used to conduct the study. Based on this information from the UW Study, the Industrial Insurance Medical Advisory Committee was not compelled to advise L&I to change its original position of non-coverage for this treatment. We submitted this technology to the State Health Technology Assessment (HTA) program for consideration. I anticipate the HTA program will ultimately review this technology allowing the Health Technology Clinical Committee (HTCC) to make a determination based on the UW Study and all other existing research.

Sincerely,

Judy Schurke
Director

cc: Bob Malooly, Assistant Director
for Insurance Services
Gary Franklin, Medical Director