Washington State Health Care Authority

Spinal Cord Stimulation – Rereview

Final evidence report: Peer review, public comment and response

October 24, 2023

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Responses to clinical and peer reviewers and public commentors

Spinal Cord Stimulation – Rereview

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Aggregate Analytics, Inc. is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only and are not within the scope of response for report accuracy and completeness.

Public comments in response to topic selection, posting of draft Key Questions and PICOTS Scope and a petition that had been made to the Health Care authority were reviewed as part topic refinement for this assessment. Many comments related to expansion of the scope to include comparisons of different modes or frequencies of SCS with each other. This potential expansion was discussed with the Health Technology Assessment Program (HTAP); the program's preference was to keep the scope of the update consistent with that of the prior report. Thus, comparisons of various SCS types, modes of delivery, etc. to each other were not part of the scope for this review update.

Public comments to the draft update report were reviewed by AAI and brought to the attention of the HTAP. There was substantial overlap between comments made to the draft report and those made during topic selection and on the draft Key Questions and PICOTS scope with many of the same suggestions, suggested citations and concerns raised. Some public comments appeared to follow the same format/form letter, most of which advocate for SCS coverage, which do not require vendor response. Comments related to methodology were grouped thematically together for response in the tables that follow. Some general responses are provided here.

Commenters expressed concern that there was no clinical input into the review. Clinician input was sought on the draft KQ and PICOTS scope and throughout the development of the report for specific clinical questions and to assist with prioritization of outcomes. Clinical experts provided peer review. Internal review was done by a clinical expert with extensive expertise in systematic review methodology and synthesis of evidence on pain management.

Commentators cited 139 distinct articles across public comment phases. All were reviewed at the title, abstract, and/or full-text level. Of these, 26 were already included in our HTA and 1 report was added as primary evidence. The other 112 did not meet inclusion criteria for this HTA, given the final PICOTS scope did not include comparisons of various forms or modes of SCS delivery with each other. The additional reference that met inclusion criteria did not change the overall strength of evidence or conclusions.

The updated review followed accepted methodology espoused by the AHRQ, IOM/NASEM, Cochrane and others. There were numerous comments requesting the removal of one cross-over trial (Hara) as not being clinically relevant based on the SCS technical factors such as thresholds used for stimulation and threshold for pain relief for permanent implantation. This methodologically strong trial met inclusion criteria set a priori. Consultation with our clinical experts suggested that there is substantial heterogeneity in devices, technical factors, stimulation thresholds, etc. in routine clinical practice given the goal of optimizing the technology for individual patients.

Specific responses pertaining to peer reviewer comments are included in **Table 1.** Draft report peer reviewers include:

- Kim Mauer, MD, Vice Chair for Pain Management & Professor of Anesthesiology and Perioperative Medicine, School of Medicine, Oregon Health and Science University
- Carl Noe, MD, Professor of Department of Pain Management and Anesthesiology & Director of Division of Pain Management, UT Southwestern Medical Center; Medical Director, Eugene McDermott Center for Pain Management.

Responses to comments posted by the Washington State Department of Labor & Industry and the Washington State Health Care Authority may be found in **Table 2.**

Responses to public comments from medical and professional organizations may be found in **Table 3.** A list of their names and associated organizations can be found in the table below.

We are also grateful to the numerous individuals who provided general public comment (i.e., not addressing evidence, project scope, or draft key questions) on the topic of spinal cord stimulation. A list of the names of those who provided comment can be found after **Table 3** below.

Responses to public comments to the posting of topic selection and the draft Key Questions and PICOTS Scope are found in **Table 4** and **Table 5** respectively.

Table 1. Responses to Clinical and Peer Reviewers

	Comment	Response
Kim Mauer		
	Specific comments	
Introduction	Page ES-1, Line 7: We may not want to say neurostimulation before TENS units. I am not sure if everyone would consider TENS units neurostimulator devices?	Thank you. We removed the word neurostimulation from the sentence as suggested.
	Page ES-1, Line 17-18: When we do SCS, the systems work so that the leads go into the epidural space but they don't reach the dorsal columns. The dorsal columns are already there and run the length of the spinal cord. The leads lay in the epidural space on top of the dorsal columns and the stimulation reaches the dorsal columns via epidural space transmission. I am probably not wording that correctly…….	Thank you for your comments. We have revised this as follows: "SCS systems involve percutaneous implantation of electrode leads into the epidural space adjacent to the dorsal column of the spinal cord".
	Page ES-1, Line 6: Reoperation reads a little funny to me. Maybe somehow word it that there is a decompression or foraminotomy and then a redo foraminotomy for the nerve root?	Thank you for your comments. We have made edits for clarity.
	Page ES-1, Lines 28-37: Excellent descriptions of high frequency and low frequency SCS systems and technology.	Thank you for your comments.
	Page ES-2, Line 18: Critically appraise seems a little bit of a weird word but the more I read it, the more it fits in appropriately I think.	Thank you for your comments.
Background	Page 9, Line 3: I really like how you started the section with the updated definition of pain.	Thank you for your comments.
	Page 9, Line 1: I really like the title "The Condition: Chronic Pain and Neuropathic Pain"	Thank you for your comments.

	Page 9, Line 33: Neuropathic pain is underdiagnosed in other conditions than just spinal disease. I am sure we all know that and don't need to know if we need to report that or not?	Thank you for your comments. We have made edits for clarity.
	Page 10, Line 6: I like how we talk about how low back pain contributes to 4.3 million years of disability annually. I also like how we compare it to any other health condition.	Thank you for your comments.
	Page 11, Line 16: I like the description of CRPS and its demographics.	Thank you for your comments.
Report Objectives and Key Questions	Page 75, Line 4: I think it was wonderful that you commented on opioid use and that is was not reported in any trial.	Thank you for your comments.
	Page 2, Line 9: When you start the section 1.4 Key Questions, I really like the chart with the PICOTS/Scope to follow. Makes sense and is easy to follow.	Thank you for your comments.
	Page ES-7, Line 1: I like the way the Key Questions are ordered. For example in Key Question (KQ) 1, I like how you labelled Crossover Trials, Key points…. It makes it easy to follow.	Thank you for your comments.
	Page ES-12, Line 4: I wonder if we need more explanation of NRSI's. We have in parentheses what it stands for but I wonder if we need more description.	Thank you for your comments. We have made edits for clarity.
Methods	Page ES-4, Line 2: On the Methods section, one sentence seems a little awkward. Maybe state and to "confirm which outcomes". Add the word "which".	Thank you for your comments. We have made edits for clarity.
	Page ES-5, Line 23: "SOE" starts that sentence but have we defined SOE yet?	Yes, SOE was defined a few paragraphs earlier.
	Page 69, Line 20: The sentence here that starts "Where" seems a little bit of an odd start to a sentence? Maybe a start that is a little more formal?	Thank you for your comments.
Results	Page ES-6, Line 1: Starting the sentence with "From" seems a little different. Maybe more of a formal sentence to start the section?	Thank you for your comments. We have made edits for clarity.
Summary Comments	Page 118, all lines: All of these lines demonstrate the organization which is great.	Thank you for your comments
	Page 131, Line 5: I like how we mention that the applicability of the findings to the U.S. healthcare system are unclear. I think it is important that we mention this because it is true in my belief.	Thank you for your comments
Overall Presentation	Page 126, Line 33: Under limitations, the sentence starts A long time horizon is employed. I wonder if we can make that sentence a little fuller?	Thank you for your comments. We have made edits as appropriate.

Quality of Report	Superior	
Additional Comments	I thought that this form was great. My only thought was if I was supposed to add more columns than provided or if I was just to fill up the amount of spots that were present.	Thank you for your comments and appreciate the feedback. We are working on a new form for future projects that will hopefully be intuitive.
Carl Noe		
	Specific Comments	
Introduction	• Yes, the overview is complete and relevant. • Yes, the topic is important due to the invasiveness and cost of these therapies. • Yes, the patient and societal concerns are covered well.	Thank you for your comments.
Background	Yes, the literature review is exhaustive and summarized well.	Thank you for your comments.
Report Objectives and Key Questions	• Yes, the goals are clear and on target. • Yes, the questions are the right ones and are answered well. • **Comments Page 1, line 10**: Please consider revising "SCS systems involve percutaneous implantation of electrode leads into the epidural space until they reach the dorsal column of the spinal cord."	Thank you for your comments. We have revised this as follows: "SCS systems involve percutaneous implantation of electrode leads into the epidural space adjacent to the dorsal column of the spinal cord".
Methods	• Yes, the methodology for study selection is sound and thorough. • Yes, the criteria for inclusion and exclusion are solid. • Yes, the risk of bias and study quality rating methods are excellent and clearly explained. • Yes, the data abstraction is extensive and the analysis and review is outstanding. • **Comment: Page 67, line 10**: Please consider adding the number of investigators reaching a consensus got "Discrepancies in ratings between reviewers were resolved through discussion and consensus."	Thank you for your comments. We have clarified this.
Results	• Yes, the amount of detail is sufficient without being overwhelming. • Yes, the key questions are answered with the best available evidence. • Yes, the tables are excellent. • Yes, the major findings are clear and substantiated. • Have gaps in the literature been dealt with adequately? I think so, but gaps in the literature are problematic.	Thank you for your comments. We have corrected the figures.

	• **Comment: Page 98, Line 1**: Fig 11 and 12 seem to show Better QoL with CMC but the text reads otherwise. "Three fair-quality RCTs reported QoL using the EQ-5D index score (scale -0.224 to 1) (Figure 11) and EQ5D overall health VAS scale (0-100) (Figure 12) at 6 months (prior to crossover)"	
Summary Comments	Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy) Yes, this is a very thorough evaluation	Thank you for your comments
Overall Presentation	• Yes, it is logically organized. • Yes, it is well written and clear. • Yes, it is very relevant. • Yes, it provides an excellent summary of a complex topic.	Thank you for your comments
Quality of Report	Superior	
Additional Comments	Comprehensive Evidence-Based Health Technology Assessment Review for the **Spinal Cord Stimulation** HTA update peer review. This review is a clinically relevant report based on a comprehensive literature review and analysis. It is valuable to policy makers who need to understand a large amount of information about a complex topic. Specifically, the introduction section provides a complete and relevant overview of the topic. This is important due to the cost and invasiveness of these therapies. The patient and societal concerns are covered well. The background section includes an exhaustive and comprehensive literature review. This is summarized very well. The objectives and key questions of the report are clear and on target. The questions are the right ones and are answered well. The methodology for study selection is sound and thorough. The criteria for inclusion and exclusion are solid. The risk of bias and study quality rating methods are excellent and clearly explained. The data abstraction is extensive and the analysis and review is outstanding.	Thank you for your comments! We are glad to note that you feel that the review is sound and clinically relevant.

	The results section is detailed but presented as to not be overwhelming. The key questions are answered with the best available evidence. The tables and figures are excellent. The major findings are clear and substantiated. Gaps in the literature have been addressed adequately but are always problematic. The summary provides a very thorough evaluation and conclusions. Overall, the presentation is well organized, well written and clear. It is clinically relevant and provides an excellent summary of a complex subject	

L&I comments on the SCS evidence report

Critical

1. There are several very positive efficacy studies in this report that are industry funded and reporting miraculous results with effect sizes never seen in any study of chronic pain. These studies should be treated as outliers in forest plot analyses and presented both with and without these studies. These studies are conducted and written by authors with serious financial conflicts of interest. It should also be pointed out the lack of any blinding whatsoever, the absence of independent assessment of outcome, and lack of independent statistical analysis.
2. There should be a mention in the limitations section that formal review of MAUDE data was not included in the report. You could mention the foibles of using this data, however that doesn't mean that there are not important safety signals of potentially severe safety issues. Along with this, there are not included some reports from official agencies on adverse events (*e.g.*, Jones et al, Spinal cord stimulators: An analysis of the adverse events reported to the Australian Therapeutic Goods Administration. J Patient Saf 2022; 18: 507-511.)
3. It is very difficult to nail down the actual cost of an SCS in individual patients, especially over a period of time (*e g.,* 5 years). The costs of care reported in the Dhruva et al study based on a nationwide sample of Optum Labs data is very important. (Dhruva et al. Long-term outcomes in use of opioids, nonpharmacologic pain interventions, and total costs of spinal cord stimulators compared with conventional medical therapy for chronic pain. JAMA Neurology 2023; 80: 18-29.). The 5 year costs, which need to include explants, electrode movement, etc in the DLI experience is likely more than $60-80,000. The Dhruva study numbers are consistent with this.

Non-critical

1. Page ES-1- "SCS was developed in the 1960's based on the Melzack and Wall's gate-control theory and has been used to treat a number of chronic pain issues", especially those related to neuropathic pain.[60,82]
2. Page ES-3, Table A- This exclusion applies to some of the included papers "Comparison of SCS combined with other interventions vs. the other intervention alone". Isn't the Kapural 2022 study and others in this category?
3. Page ES-8, ES-9, 84 and 85. "*A small improvement (increase or decrease), a moderate improvement (increase or decrease) or a large improvement (increase or decrease)*", these terms are used throughout the report, and sometimes used loosely. Do all these mean a clinically meaningful improvement? Is "a small improvement" just a statistically significant difference or a clinically meaningful improvement? Do "moderate to large effects" mean that the changes are of MCIDs? It would be helpful to define or explain the terms someway as necessary.
4. Page ES-16 and elsewhere in the table, "with greater sample size it appears to be uncommon" should be deleted as being too informal and not based on a data analysis. Similarly on P ES-17, "it seems to be rare within 30 days of implant" is also not clear-infections either do or do not occur.
5. Fig.7 on p.88. According to the original paper, the results favor SCS+CMM instead of CMM. Please review the original paper, and make sure the data is correctly presented/described in the forest plot.

6. Fig. 11 and 12 on p.98 and p.99, respectively. According to the original paper, the results favor SCS+CMM instead of CMM. Please review the original papers, and make sure the data are correctly presented/described in the forest plots.

Washington State Health Care Authority

Some general feedback:

- Could we organize the efficacy summary by indication rather than by crossover trial/parallel trial? Seems to make more sense that way? Was hard to flip back and forth within conditions
- Generally speaking there doesn't seem to be much "color commentary" on the evidence especially as compared to the Cochrane review. I know that our vendors have different approaches to this but it does make it hard to get the full context on some of the statements

Some specific issues:
If they could review the whole thing for typos with their acronyms that would be good, I found several in just the summary so they might just want to CTRL+F the whole document for the common ones.

There's a blank that needs to be addressed on page 9. Also not sure why DRAFT is all caps.

Policy Context/Reason for Selection

A Health Technology Assessment (HTA) on SCS was performed in 2010 and reviewed by the Washington Health Technology Assessment Program (HTAP). The prior report focused on evidence for the effectiveness of and complications for traditional SCS (dorsal column) in patients with chronic neuropathic pain. Signal updates were performed in 2014, 2016, and 2018, all of which concluded that there was not substantial, high-quality new evidence comparing SCS with medical or surgical interventions that did not involve neuromodulation (e.g., SCS, DRG stimulators, peripheral nerve neuromodulation) to trigger an updated report. The HTAP is interested in re-evaluation of spinal cord stimulation as additional evidence on technical advances related to use of SCSs, including use of high frequency and burst stimulation, may be available. Dorsal root ganglion stimulators will not be included in this review, given differences in lead placement compared with traditional SCS. This is consistent with the scope of the prior report. The proposed assessment update will be restricted to devices approved by the FDA for management of the FDA-approved conditions related to neuropathic and non-neuropathic musculoskeletal pain as described in the PICOTS (Table A).

The DRAFT Key Questions and Scope were published on the HTAP website in XX 2023. Public comments to the draft, related to topic nomination and a petition sent to the HCA were reviewed. None led to changes in the questions or scope following consultation with the HTA Program. All citations suggested by commenters were evaluated for inclusion based on the final key questions and scope.

This study was included/cited, but it compares high frequency SCS to traditional SCS and I thought comparisons of neuromodulators to each other were out of scope?

72. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. Anesthesiology 2015;123:851-60.

Typo page 16 – should be FBSS

- In patients with FBBS with radiculopathy treated with conventional SCS:
  - SCS was associated with large increases in the likelihood of achieving back and/or leg pain response (≥50% on VAS/NPRS) in both RCTs. Results according to pain scores were more variable but showed a moderate improvement with SCS versus CMM by 6 months across both trials (SOE: Low for all).
  - SCS was associated with a small improvement in ODI function scores at 6 months across both trials; no trial reported function responders (SOE: Low).
  - SCS was associated with a small decrease in the proportion of patients still using opioids at 6 months compared with CMM across both trials but there was no difference in the mean MME dose used (SOE: Insufficient).

Typo page 16 – should be CMM (conservative medical management)

Parallel Trials, Key points:

Chronic Back Pain

SCS vs. CCM

Three RCTs (in 5 publications) (total N=477 randomized; N range, 100 to 218)[41,51,52,58,76] and four NRSIs, two prospective comparative NRSIs (total N=391 enrolled, N range 85 to 158[70,91] and two retrospective propensity-matched database studies (total N=253,603 matched, N range 7,560 to 246,043),[20,98] compared SCS with CMM (or usual care and pain clinic in one NRSI) for the treatment of FBSS (2 RCT, all 4 NRSIs) or nonsurgical refractory back pain (NSRBP) (1 RCT).[41] The RCTs provide the primary evidence base for SOE (Table D).

Table 2. Responses to Comments Posted by the State of Washington on the Draft Report

	Specific Comments	Commenter(s)	Response
1	There are several very positive efficacy studies in this report that are industry funded and reporting miraculous results with effect sizes never seen in any study of chronic pain. These studies should be treated as outliers in forest plot analyses and presented both with and without these studies. These studies are conducted and written by authors with serious financial conflicts of interest. It should also be pointed out the lack of any blinding whatsoever, the absence of independent assessment of outcome, and lack of independent statistical analysis.	Washington State Department of Labor & Industries	There are insufficient data to do sensitivity analyses excluding industry funded studies. Industry funding and COI are noted in numerous places in the report and data abstraction. Industry funding is noted in plots. The largest effect (Kapural) is reported separately from the other studies (i.e., is not pooled with others) as it uses a different/higher frequency than the conventional SCS and the patient population differs from that of the included studies using conventional/lower frequency SCS. It is noted as being industry funded.
2	There should be a mention in the limitations section that formal review of MAUDE data was not included in the report. You could mention the foibles of using this data, however that doesn't mean that there are not important safety signals of potentially severe safety issues. Along with this, there are not included some reports from official agencies on adverse events (*e.g.*, Jones et al, Spinal cord stimulators: An analysis of the adverse events reported to the Australian Therapeutic Goods Administration. J Patient Saf 2022; 18: 507-511.)	Washington State Department of Labor & Industries	The Jones article was identified in our search and was reviewed for inclusion. It did not meet the inclusion criteria as it includes SCS for conditions/indications not included in the report; it is unclear what proportion of the reported events would be in the populations of interest to this review. Another limitation to this report is that it relies on volunteer reporting of events, making the true denominator unclear and there is the potential for misclassification of events and other variables in administrative data.
3	It is very difficult to nail down the actual cost of an SCS in individual patients, especially over a period of time (*e g.,* 5 years). The costs of care reported in the Dhruva et al study based on a nationwide sample of Optum Labs data is very	Washington State Department of Labor & Industries	This economic portion of this study does not constitute a full economic study and therefore does not meet the inclusion criteria for an economic study. They provided only

	important. (Dhruva et al. Long-term outcomes in use of opioids, nonpharmacologic pain interventions, and total costs of spinal cord stimulators compared with conventional medical therapy for chronic pain. JAMA Neurology 2023; 80: 18-29.). The 5 year costs, which need to include explants, electrode movement, etc. in the DLI experience is likely more than $60-80,000. The Dhruva study numbers are consistent with this.		a comparison of costing information so data from this portion of this study were not included in the review. Information on adverse events and opioid use from this study included in the report.
4	Page ES-1- "SCS was developed in the 1960's based on the Melzack and Wall's gate-control theory and has been used to treat a number of chronic pain issues", especially those related to neuropathic pain.	Washington State Department of Labor & Industries	Added suggested edit.
5	Page ES-3, Table A- This exclusion applies to some of the included papers "Comparison of SCS combined with other interventions vs. the other intervention alone". Isn't the Kapural 2022 study and others in this category?	Washington State Department of Labor & Industries	Consistent with the prior report, CMM was considered as "usual care", thus, Kapural meets the inclusion criteria.
6	Page ES-8, ES-9, 84 and 85. "*A small improvement (increase or decrease), a moderate improvement (increase or decrease) or a large improvement (increase or decrease)*", these terms are used throughout the report, and sometimes used loosely. Do all these mean a clinically meaningful improvement? Is "a small improvement" just a statistically significant difference or a clinically meaningful improvement? Do "moderate to large effects" mean that the changes are of MCIDs? It would be helpful to define or explain the terms someway as necessary.	Washington State Department of Labor & Industries	Additional information on determination of magnitude of effect has been added to the ES/methods. The method used is based on prior AHRQ reports on low back pain, chronic pain, and acute pain. Appendix J provides additional information on effect magnitude.
7	Page ES-16 and elsewhere in the table, "with greater sample size it appears to be	Washington State Department of Labor & Industries	This has been edited, however, the note related to sample size is intended to remind the reader that

	uncommon" should be deleted as being too informal and not based on a data analysis.		studies/sources with small sample sizes may report higher percentages of events that may be misleading (e.g., 5/10 patients is 50% of patients vs. 5/100 patients is 5%).
	Similarly on P ES-17, "it seems to be rare within 30 days of implant" is also not clear- infections either do or do not occur.	Washington State Department of Labor & Industries	The outcome is how often/frequent infections do occur and is stated in the conclusion. Some edits for clarification have been made.
8	Fig.7 on p.88. According to the original paper, the results favor SCS+CMM instead of CMM. Please review the original paper, and make sure the data is correctly presented/described in the forest plot.	Washington State Department of Labor & Industries	The text is correct. The figure has been corrected to coincide with the text.
9	Fig. 11 and 12 on p.98 and p.99, respectively. According to the original paper, the results favor SCS+CMM instead of CMM. Please review the original papers, and make sure the data are correctly presented/described in the forest plots.	Washington State Department of Labor & Industries	The text is correct. The figure has been corrected to coincide with the text.
10	Could we organize the efficacy summary by indication rather than by crossover trial/parallel trial? Seems to make more sense that way? Was hard to flip back and forth within conditions.	Washington State Health Care Authority	We have reorganized the ES according to condition.
11	Generally speaking there doesn't seem to be much "color commentary" on the evidence especially as compared to the Cochrane review. I know that our vendors have different approaches to this but it does make it hard to get the full context on some of the statements.	Washington State Health Care Authority	We generally provide the primary results/Summarize the SRs and prior HTAs for context; they are not considered primary evidence for the review which focuses on the primary studies that met our inclusion criteria and generally do not provide discussion on them. Where the Cochrane review information is noted for the cross over trials, some additional context is provided.

12	If they could review the whole thing for typos with their acronyms that would be good, I found several in just the summary so they might just want to CTRL+F the whole document for the common ones. There's a blank that needs to be addressed on page 9. Also not sure why DRAFT is all caps.	Washington State Health Care Authority	Edits and corrections have been made throughout the report.

Table 3. Responses to Public Comments on the Draft Report (Parentheses indicate individual sending the email with comments)

	Comments	Commenter(s)	Response
1	The following individuals provided experiences of living with pain treated by SCS systems, the costs from a patient's perspective, or otherwise hoping to one day gain access.	Individuals Priscilla Crutcher Erwin Pullen	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
2	The following individuals, academic institutions, or healthcare organizations provided experiences with SCS systems from a clinician's perspective.	Individuals Caroline Harstroem David Hou Matthew Kelberg Jennifer Lee Russell Legg Allen Shoham Academic Institutions Jiang Wu[*] Healthcare organizations Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
3	SCS compared to CMM may not be useful in patients that have already failed other treatment options.	Device manufacturer Todd Davis[‡]	Thank you for your perspective.
4	KQ4 did not capture recent cost-effectiveness publication for EVOKE SCS system. Duarte RV, Bentley A, Soliday N, Leitner A, Gulve A, Staats PS, Sayed D, Falowski SM, Hunter CW, Taylor RS. Cost-utility Analysis of Evoke Closed-loop Spinal Cord Stimulation for Chronic Back and Leg Pain. Clin J Pain. 2023 Oct 1;39(10):551-559. doi: 10.1097/AJP.0000000000001146. PMID: 37440335; PMCID: PMC10498882.	Device manufacturer Todd Davis[‡]	This study was published after the search dates for the review. This study does not meet inclusion criteria stated in the PICOTS; it compares open and closed loop SCS.
5	The following individuals, academic institutions, device manufacturers, associations, or healthcare organizations disagreed with the selection of evidence, and suggested certain publications be removed and others be added. There was often disagreement or confusion about methodology used in the review, and concerns about the use of SOE.	Individuals Caroline Harstroem Joe Kim Jennifer Lee Allen Shoham Academic institutions Brett Stacey[*] (Ian Goodhew) G. Burkhard Mackensen[*]	Evidence selection was based on the final KQ and PICOTS which were set a priori and published and the review is based on accepted standards for systematic review (e.g., AHRQ, IOM/NAM, Cochrane). Prior to publishing the final KQ and PICOTS, all public

		Device manfucaturer Todd Davis[‡] Ashwini D. Sharan[††] (Christine Ricker) David Caraway[‡‡] (Sandeep Patil) Nileshkumar Patel[§§] Associations and societies Kirsten Tullia[§] Amol Soin[**] Keri Kramer[***] Healthcare organizations Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	comments from topic selection, draft key question/PICOTS posting and a petition to the HCA were reviewed, and AAI sought clinical input. All of this was discussed with the HTAP program. All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. Reasons for study exclusion at full text are in the appendix. From the comments, there may be a lack of clarity or lack of understanding regarding the methodologic criteria for evaluation of study risk of bias and determination of SOE. Methods for study risk of bias evaluation and determination of SOE are described in the full report and follow accepted methods and practice (AHRQ, IOM/NAM, Cochrane, GRADE); edits have been made for clarity. Appendix D contains additional information.
6	The following Associations or device manufacturers had specific concerns over the exclusion of RCTs comparing different SCS waveforms.	Associations and societies Amol Soin[**] Device manufacturer Ashwini D. Sharan[††] (Christine Ricker) David Caraway[‡‡]	Evidence selection was based on the final KQ and PICOTS which were set a priori and published and the review is based on accepted standards for systematic review (e.g., AHRQ, IOM/NASEM, Cochrane). Comparison of different SCS modes of operation, waveforms or frequencies was not part of the review scope.

7	Specific concerns over exclusion of Petersen 2023 and Kapural 2022: Report cites lack of comparator after 6 months. "These RCTs were designed in a pragmatic fashion, like the way many patients present to health care providers in real-world settings – not having a crossover option or forcing patients failing conventional medical management to remain with an unsatisfactory treatment for one or two years is neither ethical nor practical when considering the way treatment decisions are made for late or last resort therapies such as SCS."	Device manufacturer David Caraway[‡‡]	The intent of the review is to provide comparison of SCS with the comparators listed in the PICOTS. The longer follow-up in studies reporting across all patients who received SCS after they were allowed to cross over is not comparative (essentially a case series/single arm study). We have noted the results of the longer follow-up (to include those for Kapural 2022) in the report as well as related attrition/loss to follow-up at longer times which are important to consider. Results that were not comparative were not considered part of SOE. Petersen 2023 was not captured in our original search and has been added to the report. Petersen 2023 is a follow-up publication to Petersen 2021 (SENZA-PDN trial) which was already included in the report. Petersen 2023 provides 24-month follow-up data and is essentially a case series of SCS; it was only included for safety and data for effectiveness outcomes are provided in Appendix F, Table F3 for completeness but are not detailed in the report.
8	The following individuals, academic institutions, device manufacturers, associations, or healthcare organizations suggested specific RCTs and/or SRs of RCTs to be included in the report.	Individuals Christina Julian Jennifer Lee Academic institutions Jiang Wu[*]	All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. No new studies were added. (Note: one follow-

		Device manufacturer Todd Davis[‡] Ashwini D. Sharan[††] (Christine Ricker) Nileshkumar Patel[§§] Associations and societies Amol Soin[**] Healthcare organizations Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	up publication [Petersen 2023] to a trial already included in the report [Petersen 2021] was added. This study was essentially a case series of SCS at 24 months and was only included for safety; data for effectiveness outcomes are provided in Appendix F, Table F3 for completeness but are not detailed in the report.) Reasons for study exclusion at full text are in Table C1 of Appendix C (citations marked with an asterisk were proposed during public comment).
9	The following individuals, academic institutions, device manufacturers, associations, or healthcare organizations, made specific requests to the Washington State Healthcare Authority urging them to cover SCS.	Individuals Paul Dejulio Sam Elghor Caroline Harstroem John Hatheway David Hou Nicholas Juan Christina Julian Matthew Kelberg Joe Kim Daniel Kwon Jennifer Lee Allen Shoham Academic institutions Yian Chen[*] Device manufacturer Ashwini D. Sharan[††] (Christine Ricker) Nileshkumar Patel[§§] Associations and societies Kirsten Tullia[§] Jennifer Lee[†††] Michael Leong[†††] Amol Soin[**] Healthcare organizations	Comments pertaining to formulation of policy do not require a response by the evidence vendor. The vendor does not suggest, recommend, determine, or evaluate coverage policy.

		Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	
10	The following academic institutions, device manufacturers, and associations cited flaws in studies included in the report, with specific comments on Hara 2022, Sokal 2020, and Al-Kaisy 2018: - Hara 2022: Specific pattern of stimulation shown to be equivalent to Sham - Sokal 2020: Trial underpowered, small sample, heterogenous population, - Al-Kaisy 2018: Two of the frequencies are not available in the US and not relevant to Washington. - Hollingworth 2011 - Turner 2010	Academic institutions Brett Stacey[*] (Ian Goodhew) G. Burkhard Mackensen[*] Device manufacturer Ashwini D. Sharan[††] (Christine Ricker) David Caraway[‡‡] Nileshkumar Patel[§§] Associations and societies Amol Soin[**] Keri Kramer[***]	Commentaries, editorials, and similar publications are not part of the PICOTS inclusion criteria for the review. In general, it has been observed that there are a variety of criticisms of studies that present differing perspectives on the evidence in any given study or review as do author responses to such criticisms (e.g., reply by Gulati, et. al, JAMA March 14, 2023 Volume 329, Number 10). All studies have strengths and limitations. This update review focuses on evidence presented in studies meeting inclusion criteria. All studies listed met the inclusion criteria set a priori. Critical appraisal of these studies based on generally accepted study methodological criteria are provided in the report and appendices Consultation with clinical experts for this review indicated that it is unclear how comparable or applicable the parameters used in the RCTs are to usual clinical practice and that there is likely substantial heterogeneity in what is used clinically, and SCS delivery parameters are tailored to the patient. All included studies had some potential for bias and technical factors that may

			limit their applicability to other populations. One trial (Al-Kaisy) used a trial-specific program for stimulation that limits its applicability to broader clinical use for example.
11	Specific concern that Hara 2022 was graded better than Kapural 2022.	Device manufacturer David Caraway[‡‡]	Criteria for individual study risk of bias based on study methodology and study design are found in the report and in appendix D.
12	Concern that risk of bias assessments looked at industry funding.	Device manufacturer David Caraway[‡‡]	Criteria for individual study risk of bias and for determining SOE are found in the report and appendix. Neither ROB nor SOE include criteria related to industry funding; it is not considered in either.
13	The following individuals, academic institutions, device manufacturers, or associations expressed concern that "sound clinical judgement" did not inform the review, that the AAI team lacks clinical experience, that clinicians were not involved in the report, or other concerns related to clinical experience.	Individuals Nicholas Juan Academic institutions Brett Stacey[*] (Ian Goodhew) G. Burkhard Mackensen[*] Jiang Wu[*] Device manufacturer Kirsten Tullia[§] Nileshkumar Patel[§§] Associations and societies Keri Kramer[***]	Clinicians with expertise in pain management and in systematic review methodology were involved in topic refinement and provided input on clinical questions posed by the SR team throughout report development. Clinical expert peer review and internal review were obtained on the DRAFT report and incorporated into the final report.
14	The following device manufacturers or associations expressed concern over Incomplete and/or missing payer policies, guidelines, and/or HTAs, including: ECRI, BCBS Evidence Street, Hayes, American Society of Interventional Pain Physicians, American Society of Anesthesiologists, American Pain Society and Neuromodulation Therapy Access Coalition. There were additional specific comments: - HTAs summarized compared "new" waveforms, specifically closed-loop SCS and high-frequency SCS vs. "older" waveforms. Concern that this is specifically excluded in	Device manufacturer Ashwini D. Sharan[††] (Christine Ricker) David Caraway[‡‡] Associations and societies Kirsten Tullia[§]	Payer policies: Per the vendor contract with the State, the CMS NCD and information from a minimum of two bellwether payers are included in the report. The HAS report has been added. It is not a full technology assessment and provides limited information regarding the evidence base.

	rereview, and why these HTAs were presented. - Concern over why HAS (France) and NICE (UK) not listed, which present SCS vs. CMM. - Several other payers with coverage policies available: Premera Blue Cross, UnitedHealthcare, Molina Healthcare, Regence Blue Shield, Centene Corporation, Community Health Plan of Washington, Elevance Health, Providence Health Plan, Kaiser, Humana. - report does not reference multiple professional society guidelines: American Society of Interventional Pain Physicians (ASIPP), American Society of Anesthesiologists, American Pain Society, Neuromodulation Therapy Access Coalition, American Society of Regional Anesthesia and Pain Medicine (ASRA), US Department of Health & Human Services Pain Management Best Practices Inter-Agency Task Force Report (2019). - Publication from 2004 that is historic Washington State evidence.		The NICE guidelines are device specific reports, and not full technology assessments across types of SCS. They were added to the summary table of government reports for completeness. They both refer to the 2008 NICE guideline which is included in the report. The report does provide information on clinical guidelines specific to the topic and includes those listed if they were specific to the topic. We have also included guidelines that were part of the prior report in an appendix. Guidelines are not considered primary evidence for this HTA. They are listed as required by the scope of work.
15	Specific concern about requirement for KQ3 for an RCT to show differential effectiveness. Request that two sub-populations of patients are developed to create separate sub-analyses for Workers' Compensation and health benefit coverage populations based on the differential effectiveness in the two population; to be performed in a manner that the findings of Hollingworth are not applied to a health benefit coverage population.	<u>Associations and societies</u> Keri Kramer***	There are insufficient data to do subgroup analyses to evaluate differential effectiveness or safety. Patient populations are described in the report and data abstraction. Evaluation of differential effectiveness or safety based on patient characteristics or population characteristics involves looking for effect modification (statistical interaction) between treatment and such characteristics/variables. Rationale is for requiring RCT evidence is based on the following citations (and

			others) in addition to accepted methodology: • Schandelmaier, et. al. *CMAJ* 2020 August 10;192:E901-6. doi: 10.1503/cmaj.200077 • Dettori, et.al, Evid Based Spine Care J. May 2011;2(2):7-10 1. Causal inference is not possible w/NRSI: NRSIs generally do not allow causal inference to be drawn; at best associations can be identified. Even with some of the newer modeling methods for NRSIs, which most of the lit we deal with do not do, there are concerns about the accuracy "causal modeling" even in the best of circumstances. 2. NRSI are subject to selection bias, confounding by indication, impact of know/unknown confounders. 3. Subgroup analyses are often spurious in even in RCTs - and in RCTS there is at least a reasonable chance that known and unknown confounders may be controlled and some level of causal inference is possible.
16	Specific concern that layout of report includes sections with no explanatory text. Section 2.7 includes a table 3 but not text. Request to include statement that "all ten published Clinical Guidelines support the role of SCS as a SoC procedure".	Associations and societies Keri Kramer***	The guidelines and payer policies are listed for background and reference per vendor practice as requested in the scope of work.
17	Specific concern that there is a bias in section 2.9 that underreports health plans coverage of SCS, and no explanatory text.	Associations and societies Keri Kramer***	Payer policies: Per the vendor contract with the State, the CMS NCD and

	- Includes table 6 but not text. - Concern that there is no information about Washington being the only state that does not cover SCS. - Request that explanatory text be added to section 2.9 to include information about health benefit plans in the US including SCS.		information from a minimum of two bellwether payers are included in the report. It is not the role of the vendor to provide exhaustive lists of payer policies or to discuss them.
18	Specific request to include the following studies of SCS vs. other interventions: - Deer 2017 - Hamm-Faber 2020 - Mekhail 2020 - North 2020 - Breel 2021 - Fishman 2021 - Metzger 2021 - Petersen 2023 - Wallace 2023	Associations and societies Keri Kramer***	Evidence selection was based on the final KQ and PICOTS which were set a priori and published. The review is based on accepted standards for systematic review (e.g., AHRQ, IOM/NAM, Cochrane). Comparison of different SCS modes of operation, waveforms or frequencies was not part of the review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS. All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. Petersen 2023 was not captured in our original search and has been added to the report. Petersen 2023 is a follow-up publication to Petersen 2021 (SENZA-PDN trial) which was already included in the report. Petersen 2023 provides 24-month follow-up data and is essentially a case series of SCS; it was only included for safety and data for effectiveness outcomes are provided in Appendix F, Table F3 for completeness but are not detailed in the report. All other publications suggested did not meet

			inclusion criteria. Reasons for study exclusion at full text are in Appendix C (citations marked with an asterisk were proposed during public comment).
19	Request that Hara be removed from report. Also that Hollingworth 2011 be classified no higher in terms of SOE than Turner, and that Turner is classified as low.	Associations and societies Keri Kramer***	Evidence selection was based on the final KQ and PICOTS which were set *a priori* and published. The review is based on accepted standards for systematic review (e.g., AHRQ, IOM/NAM, Cochrane). The Hara study met inclusion criteria. Study risk of bias and SOE are different concepts. No SOE is provided for economic studies (Hollingworth is an economic study). Individual study risk of bias for studies of treatment and economic studies are different given vast differences in methods. Risk of bias for all types of studies (and for SOE) and are described in the report and in Appendix J.
20	Request that Ho 2022 be included in summary of SRs, and that O'Connell and Traeger are removed.	Associations and societies Keri Kramer***	There is substantial overlap in studies included in Ho, Traeger and O'Connell. The reviews by Traeger and O'Connell generally follow accepted rigorous methodologic standards for systematic review, including criteria suggested in the AMSTAR-2. Ho 2022 was already included in the table summarizing systematic reviews. It should be noted that the review by Ho 2022 included critical

			weaknesses as indicated by AMSTAR-2: a lack of clarity on protocol and no list of excluded studies, as well as a failure to address risk of bias in the discussion or publication bias. Additional non-critical flaws included no discussion on funding or heterogeneity of studies.
21	Request that WSHCA provides the ICER value threshold that it uses for making decisions based on cost-effectiveness data.	Associations and societies Keri Kramer***	Suggestion or determination of healthcare or coverage policy, including any specific cost-effectiveness threshold, is not the purview of the vendor.
Public comments posted after the October 2nd, 2023 deadline			
1	The following individuals provided experiences of living with pain treated by SCS systems, the costs from a patient's perspective, or otherwise hoping to one day gain access.	Individuals Mary Pullen Becky Brooks	Comments pertaining to formulation of policy do not require a response by the evidence vendor.
2	The following individual provided experiences with SCS systems from a clinician's perspective.	Individual Janmeet Sahota	Thank you for your perspective.
3	The following individuals or associations made specific requests to the Washington State Healthcare Authority urging them to cover SCS.	Individuals Janmeet Sahota Association and societies Daniel Waldmann‡‡‡	Comments pertaining to formulation of policy do not require a response by the evidence vendor.
4	Incomplete, missing payer policies, guidelines, and/or HTAs.	Association and societies Daniel Waldmann‡‡‡	Payer policies: Per the vendor contract with the State, the CMS NCD and information from a minimum of two bellwether payers were included. It is not the role of the vendor to provide exhaustive lists of payer policies or to discuss them.
5	Disagreement with selection of evidence; should include others and/or exclude some.	Individual Janmeet Sahota	Evidence selection was based on the final KQ and PICOTS which were set *a priori* and published. The review is based on accepted standards for systematic review (e.g., AHRQ, IOM/NAM, Cochrane).

			All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. Reasons for study exclusion at full text are in the appendix.

AAI = Aggregate Analytics Inc.; AHRQ ; Agency for Healthcare Research and Quality; CMM = Conventional medical management; ES = Executive summary; HCA = Health Care Authority; HTA = Health Technology Assessment; HTAP = Health Technology Assessment Program; KQ = Key Question; L&I = Labor & Industries; MCID = Minimal clinically important differences; RCT = Randomized control trial; SCS = Spinal cord stimulator; SOC = Standard of care; SOE = Strength of Evidence; SR = Systematic review.

*Associated with the University of Washington.

† Associated with and/or on behalf of Providence Health.

‡ Associated with and/or on behalf of Saluda Medical.

§ Associated with and/or on behalf of Advanced Medical Technology Association.

** Associated with and/or on behalf of the American Society of Interventional Pain Physicians.

†† Associated with and/or on behalf of Medtronic.

‡‡ Associated with and/or on behalf of Nevro Corp.

§§ Associated with and/or on behalf of Boston Scientific.

*** Associated with and/or on behalf of North American Neuromodulation Society.

††† Associated with and/or on behalf of the Pacific Spine Pain Society.

‡‡‡ Associated with and/or on behalf of the Medical Device Manufacturers Association.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: HCA Health Technology Assessment
Date: Thursday, September 28, 2023 9:05:40 AM

External Email

I was surprised to learn that Washington is the only state that does not approve spinal cord stimulation (SCS) for any diagnosis for any patient with insurance covered by the Health Care Authority (about 2.5 million Washingtonians). Thankfully the Health Technology Clinical Committee has developed an evidence report published in September 2023 and will review evidence, comments, and expert guidance to make coverage decisions.

Thank you for allowing me to participate as a patient in this very important review. I realize that my story is just one person, but I am hopeful that my words may have some impact on the insurance approval of SCS for all patients in Washington. I am a retired business professional and realize that there are both humanitarian considerations and the cost of the procedure that needs to be considered.

First I would like to address the major medical billings for the spinal procedures I had in the last 36 months prior to my SCS implant.

1. Ten Injections: $35,399.23.
2. Two sets of Ablations: $13,133.
3. L4-L5 Infusion: $104,242 (Scoliosis)
4. Physical Therapy and Home Health Care: $17,355.

The billings for all related X-Rays, CT Scans, MRI'S, Nuclear Med Scan ($5318), and endless doctor appointments for each procedure are not included nor are the injections, ablations, and laminectomy prior to the last 36 months.

Procedures 1-4 (Total Cost = $170,129.23) were not effective in pain relief which means my once very active life continued to be limited.

Where my personal treatment may be considered strictly humanitarian due to my age, I think it is important to think about our younger generation who may be on permanent disability from a personal or work related injury, the cost to insurance companies for ineffective pain management procedures and mental health treatment, not to forget the Opioid crisis that America now faces.

My neighbor who is a Board Member of Evergreen Medical Center thankfully recommended I explore further pain management options with Dr. Jennifer Lee, Acute Pain Therapies and together we concluded that SCS could be beneficial. On, 08/17/2023, the SCS surgery was successfully completed.

The collaboration between Dr. Jennifer Lee with Theresa Shrewsberry, Territory Manager Neuromodulation for Boston Scientific, is noteworthy. Barely a month out from the surgery date, keeping in mind a waiting period for incision healing before the machine was programmed, I am feeling my first sense of pain reduction. Where we are still in the trial/error period, I just returned from a trip to Boise and was able to walk 1.5 miles each day which would have been impossible before the implant. Of course, this did not mean it was painless, certainly, but manageable. I am

100% positive with the aid of Dr. Lee and Theresa, I plan be able to return to being able to return to my former life with reduced medical expenses.

From a humanitarian standpoint, imagine the impact of SCS for approximately 2.5 million people in Washington who now live with chronic pain and can not afford the procedure as it is not covered by their insurance. From a fiscal standpoint, Government spending could reduce from the people who prefer to return to work to be productive rather than living on disability. Mental health expenses could reduce at the same rate, because independent people should feel empowered about their resiliency. SCS could reduce the opioid crisis in this country using electrical impulse as opposed to drug dependency to ease chronic pain.

I realize the insurance industry would not save all $170,129.23+ in medical billings in my case as it is prudent for doctors to proceed first with physical therapy and less invasive procedures. However, had I not had the option of insured SCS, my one remaining choice would be a multilevel back fusion from T10 to S1 which was not recommended by my surgeon nor would I take the risk. Imagine the risk to life with no guarantee of pain relief to all who do not have the benefit of SCS insurance coverage. The Fusion of L4-L5 billing was as stated above as $104,242. Where I was not quoted the billing of the multilevel fusion, had I not had the insured option for SCS, the cost of a multilevel back fusion would be staggering. The human cost would be dear to an uninsured person and the the cost of SCS would pale in comparison to this substantial operation expense.

I am convinced that SCS insurance coverage would not only improve the lives of so many who live in chronic pain, but would be a fiscally prudent decision for all insurance carriers.

Thank you for listening. I sincerely appreciate your consideration.

Warm Regards,

Priscilla Crutcher
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Spinal Cord Stimulator Comments
Date: Thursday, October 5, 2023 4:05:59 PM

External Email

To Whom It May Concern:

I am writing to express my strong support of providing coverage for making Spinal Cord Stimulator technology available to all Washington State Health Care Authority members as well as all individuals suffering from a wide variety of neuropathic, sciatic, and other afflictions. I have had 3 back surgeries since 2000, all of which helped for a brief time but eventually lost their effectiveness. Besides surgeries, I have tried chiropractic treatments, acupuncture, physical therapy, and numerous cortisone spinal epidurals. None of these procedures brought any relief.

At age 72, I found myself barely able to walk more than 50 feet before pain and cramping made further movement impossible. I had greatly decreased stability and suffered a number of falls as a result. Going to the grocery store was almost more than I could bear and only accomplished by leaning heavily on my shopping cart. Even then, I had to stop every few paces. People would come up to me and ask if I was OK. Some of them even offered me the business cards of their chiropractors or physicians. All that is to say that my condition was extremely dire. The last option offered to me by an orthopedic surgeon was to fuse my entire lumbar spine; a two-day extremely dangerous operation.

Fortunately, I had the good fortune to meet Dr. Jennifer Lee from Acute Pain Therapies. After taking a conservative approach and trying several spinal injections that did not yield any lasting results, Dr. Lee discussed with me the possibility of having a Spinal Cord Stimulator trial using Boston Scientific's SCS system. She cautioned me that since my primary diagnosis was spinal stenosis, SCS might not yield as good a result as other conditions, e.g., sciatica. I participated in a one week trial and the results were miraculous. All of the pain in my lower back, hips, and thighs disappeared. I no longer had neuropathy symptoms and was immediately able to stop taking gabapentin (600 mg/night). I was able to walk and move without pain. The only sad part was that after the trial, the SCS device was removed and I had to wait for approval to get the permanent system implanted, which Dr. Lee performed this last Monday, 10/5/2023.

It is an extremely easy and quick procedure (1 1/2 hrs) compared to the other, life-threatening options I was given. Thanks to Dr. Lee's skill and the Boston Scientific SCS system, I have my life back. I would hate to think that any one, despite their insurance coverage, would be denied access to this technology. The life-changing benefits far outstrip the cost of the procedure, which in the long run is far less dangerous than other treatments as well as less expensive over the long haul given the cost of injections, medications, alternative methodologies that are temporary and minimally effective at best.

I hope that you will take my comments and experience into consideration as you weigh

making this wonderful technology available to Washington's HCA population as other states have done. It is a practical, less expensive, and most of all immediately effective tool that can bring relief to thousands of our fellow citizens who suffer debilitating back pain. Please, do the right thing.

Sincerely,

Erwin Pullen

P.S. - Please consider my comments even though I am submitting them slightly past the 10/2 deadline. I thought it would be only appropriate to share my thoughts AFTER having receive my permanent implant on 10/5.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS Response letter
Date: Monday, October 2, 2023 7:49:04 PM
Attachments: WA HTA Physician Response.pdf

External Email

Dear Committee Members,

Please see attached response letter to the SCS decision.

Kind regards,

--
Caroline A. Harstroem, M.D.
Interventional Pain Specialist

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: RE: SCS coverage in WA state
Date: Tuesday, September 26, 2023 4:10:20 PM

External Email

Subject: Request for Enhanced Coverage of Spinal Cord Stimulator for Chronic Spine Pain Patients

Dear Committee,
I am writing to bring your attention to a matter of great significance concerning healthcare coverage for the hardworking residents of Washington State, particularly those enduring the challenges of chronic spine pain and chronic neuropathic pain. My name is Dr. David Hou, and I am an interventional pain physician practicing in Washington State. The purpose of this letter is to passionately advocate for enhanced insurance coverage for spinal cord stimulation (SCS) as a highly effective treatment option for these individuals.
Washington State is home to a significant population grappling with the debilitating effects of chronic spine pain and neuropathic pain. As a medical professional intimately familiar with this reality, I have witnessed firsthand the transformative potential of spinal cord stimulation. Multiple well-conducted, randomized, multi-center clinical trials unequivocally attest to the efficacy of this procedure in alleviating suffering and enhancing the quality of life for patients enduring chronic pain.

In my personal practice, I have had the privilege of seeing remarkable improvements in patients' lives through the utilization of spinal cord stimulators. I would like to share a recent and poignant case that vividly illustrates the profound impact this technology can have on an individual's well-being. Last week in my practice, Teresa, a patient who resides in a semi-truck with her husband - a hardworking truck driver - faced immense challenges due to her failed back surgical syndrome. After undergoing a spinal cord stimulator trial with a Medtronic device, she experienced an astonishing respite from her pain during the trial period. This relief was both unexpected and transformative, enabling her to regain her mobility and significantly enhance her overall quality of life.

During her follow-up appointment at my clinic, Teresa was overwhelmed with joy and relief. Tears welled up in her eyes as she expressed her astonishment and happiness at the successful pain control she had experienced. She vividly described the profound change in her life, exclaiming that she had no pain and could hardly believe the incredible improvement. Her ability to move freely without the shackles of pain left her in a state of disbelief and immeasurable gratitude.

These stories shed light on the struggles of hardworking citizens who face not only the burden of chronic pain but also financial constraints due to their living circumstances. The accessibility of spinal cord stimulation can significantly impact their ability to continue their important work while enjoying an improved quality of life.

I sincerely appreciate the dedicated efforts of the Washington State Insurance Committee in

evaluating the potential benefits of increasing coverage for spinal cord stimulator procedures. Your careful consideration of this matter highlights your commitment to enhancing the well-being of the residents of Washington State. By expanding insurance coverage for this procedure, we can collectively make a substantial difference in the lives of countless individuals struggling with chronic pain.

Thank you for your attention to this critical matter. I am optimistic that our collaborative efforts can lead to a positive and impactful change in healthcare policy, ultimately benefiting the health and well-being of our hardworking community.

Sincerely,

David Hou, MD

From: Acklin, Brian [redacted]
Sent: Tuesday, September 26, 2023 3:26 PM
To: Christopher Godbout [redacted]
Cc: Kilpatrick, Austin [redacted]
Subject: SCS coverage in WA state

Hi Dr. Godbout and Dr. Hou,

I am certain you have heard about the efforts to expand coverage of spinal cord stimulation in the state of Washington to include state employees and Medicaid. I want to encourage you both to join Medtronic, PSPS, NANS and others in the state and country by submitting a comment in support. Both the volume of comments and quality of comments are meaningful ways we can make a difference - share a patient story or even an anecdotal experience of SCS outcomes, they all make a difference.

Dead line to comment: Monday Oct 2, 2023
Comments may be submitted to: shtap@hca.wa.gov

Thanks in advance for support patient access with a comment.

Best Regards,

Brian Acklin
District Sales Manager | PNW

Medtronic
Pain & Interventional Therapies
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS Comment
Date: Monday, October 2, 2023 2:37:59 PM

External Email

Dear committee members,

I am a pain physician practicing in Seattle, Washington. Prior to this, I trained in pain medicine in Portland, Oregon. I have seen many patients derive remarkable benefit from spinal cord stimulation. These patients have had conditions such as failed back surgery syndrome, lower extremity radicular pain, upper extremity radicular pain, diabetic neuropathy pain, and trigeminal neuralgia. Unfortunately, I have also seen many patients who MIGHT have benefited from spinal cord stimulation therapy, if only their insurance (issued by the state of Washington) had covered the procedure.

I am therefore writing to request that you recommend that SCS be covered by Washington state insurance. Currently, Washington is the only state that denies this technology to its citizens. I believe it is long past time to change that.

Matthew Kelberg, MD

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS HTA response
Date: Tuesday, September 26, 2023 8:12:28 PM
Attachments: Personal HTA.odt

External Email

I have included in the attachment above, my response and comments to the HTA SCS response.

Thank you for considering my input,
Jennifer M Lee, MD

Health Technology Assessment Committee,

As a full-time, board-certified Pain Management physician of 12 years, I have passion for assisting patients who suffer in chronic pain to find safe and efficacious treatments. My concerns are the reduction of pain and also restoration of function while minimizing risk. I care for all spectrum of patients though the 'call to action' that inspired my engagement in this HTA application concerning spinal cord stimulation involves Mr. S.

Mr. S. became a patient of mine 2 years after his initial injury and onset of pain. He had been working as a laborer on a construction site when he fell and suffered a tibial ankle fracture. Though he healed as expected from the surgical correction to this injury, Mr. S. developed Complex Regional Pain Syndrome. Despite treatment with physical therapy, multiple medication trials, mirror-therapy, behavioral health pain management strategies, his pain was severe. He was unable to return due to the severity of his pain. The medical evidence strongly indicates that spinal cord stimulation is the next appropriate step in managing his care though the current L&I coverage policy denies this. If this patient were insured with any private insurer, Medicare, or any other state's L&I coverage he would be eligible to receive this treatment.

I am grateful for the Health Technology Assessment committee's willingness to review the most current literature on spinal cord stimulation though I harbor concerns with their methods and and analysis. The HTA committee's review of literature identified only one multicenter, cross-over RCT of SCS vs sham in patients with CRPS (10). This study was included 33 subjects who received a range of stimulation frequencies and patterns. With a thoughtful and robust study design, this study was powered to supply statistic significance for all analyses. The results showed significant differeces in pain scores (including VAS, all scales of MPQ & both scales of GPE) for all neuromodulation settings compared to placebo. Additionally, there were no differences in pain scores when the stimulation was turned off. The HTA seems to acknowledge these positive findings however in contrary to this, the summary Table C states that the strength of evidence (SOE) was insufficient. Explanation of this 'Insufficient SOE' determination is desired.

Another criticism of implied in Table C, is the lack of intermediate or long term evidence. This study did not fail to show a lack of evidence, rather it's design was not intended to explore this outcome. It could be argued that RCTs are not the ideal study design to examine this outcome. Other publications have studied this outcome, including a prospective examination of 84 consecutive patients with CRPS type I who received SCS (8). Among these subjects, 12 years after implantation, 63% (95% CI:41-85) continued to report effective pain relief.

Kumar also reported on long term benefits of SCS among CRPS patients in a retrospective study of 25 patients (11). Parameters for evvaluation reflected pain assessment as well as functional measurements (VAS, ODI, BDI, EuroQoL-5D, SF-36 and drug consumption). At 88 months after implantation, benefits in all categories were maintained with statistical significance ($P < 0.001$) compared to baseline. Notably, the best results were observed among younger patients who received SCS within 1 year of disease onset.

The HTA did include 2 RCTs that compared SCS vs PT or CMM for the treatment of CRPS (1,4-6). Each of these studies published large-moderate reductions in pain at the 24 month time point. Sixty month data included only 50% of the original subjects and was therefore inadequately powered to deliver conclusive outcomes. Regarding functional scores, moderate to small improvements in ODI were reported among the treatment group. Additionally, it should be noted that among research studies examining outcomes from alternative treatments for CRPS, 60 months is an ambitious time point that is extremely rarely reported. The authors also describe the study comparing HF (10kHz) SCS to CMM as being a poor-quality RCT though still include the data in summary of evidence (Table G). If it is determined to be poor-quality, it would stand to reason that the data not be considered. Again, similar to the behavior observed in Table C, despite seemingly positive findings of the studies in text summary, the HTA committee declares 'Insufficient SOE' in Table G without definition for how this conclusion is reached.

Another Key Question of the HTA assessment is the issue of safety of SCS as a technology. Spinal cord stimulation has been a treatment for refractory neuropathic pain for greater than 30 years. As expected during the lifetime of a therapy, its safety has improved. There is a substantive amount of data on this topic. The HTA response is contradictory in its discussion of its study selection in considering this key question. While it states 'inclusion of nonrandomized studies with large sample sizes permitted evaluation of uncommon an rare events,' the HTA seems to immediately delegitimize these studies by claiming there is a 'risk of bias across nonrandomized studies.' Though it is true that no source is perfect, in examining a complex & meaningful topic, it is essential to be open-minded to considering the value of various sources of evidence and examining the sum as a whole.

The spirit of this Key Question is concerning safety of patients who undergo SCS. The term adverse event (AE) is a broad term which includes many events that may be reported during a research trial. Many of these reported AEs are not threats to the safety of the patients. Examples include but are not limited to: electrode dislocation, charging difficulties, requirement for reprogramming, & itch/rash. The significant AEs that are of relevance to safety assessment of SCS include infection, neurologic injury and hematoma.

To this interest, a large retrospective study including pharmay claims from US commercial and

Medicare Advantage enrollees who underwent SCS was recently reported in JAMA Neurology (3). Among 1290 patients, the incidence of infection was 2.1%. In a recent RCT involving 50 patients with SCS implanation, the frequency of deep surgical site infection requiring explantation was 2% (9). Another author reported an incidence more serious complications including dural puncture, neurologic damage and infection to be 2-4% in the US, with 1/3 of these infections being superficial and not requiring explantation (4). Even lower neurologic injury rates were reported by Cameron, with epidural hematoma incidence of 0.3% & paralysis incidence of 0.03% (2). Furthermore, among those RCTs that were reviewed by the HTA, it is important to note that there were no difference in withdrawals due to AEs between SCS and comparative treatments.

My patient, Mr. S. remains in pain and in limbo. He still suffers with neuropathic pain preventing his ability to return to work. The impact of this on his mental health & his family's socioeconomic stability is difficult to witness. This is especially the case, knowing that he is being withheld the opportunity for a trial of spinal cord stimulation.

It is my request that the Health Technology Assessment committee give unbiased consideraton for spinal cord stimulation coverage. The fact that the State of Washington's coverage policies are far out of alignment with other state policies in the nation, Medicare and private insurers is deserving of reflection. Patients who suffer in chronic, refractory pain such as would be eligible for this therapy are vulnerable and dependent on the judgment of this committee.

Sincerely,

Jennifer M Lee, MD

Pain Management, Anesthesiology

Acute Pain Therapies

Bellevue, WA

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Spinal cord stimulator coverage
Date: Wednesday, September 27, 2023 11:15:54 AM

External Email

I am a practicing pain management physician in Washington State. I am board certified in both anesthesia and pain medicine. I have seen many patients who have had multiple back surgeries as well as injections and other treatments, but still in pain. Currently those with state insurance or workers comp are left with opioids which is often not effective and creates a slew of other issues. I would love to see spinal cord stimulation as a non-opioid alternative for these patients. Thank you.

Russell Legg

northwest
PAIN SPECIALISTS

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation
Date: Tuesday, September 26, 2023 9:29:27 AM
Attachments: WA HTA shoham.docx

External Email

My name is Allen Shoham , MD. I am a physician in Richland Washington. Please see my attached letter regarding spinal cord stimulation coverage in the state.

Sent from Mail for Windows

VIA electronic mail: shtap@hca.wa.gov

September 26, 2023

Washington Health Care Authority
Attn: Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712

Re: Draft HTA Report for Spinal Cord Stimulation (SCS)

Dear HTA Review Committee:

I am Dr. Allen Shoham, MD. I am a board-certified interventional pain physician and anesthesiologist working as a full-time interventional pain physician in Richland Washington for over 11 years.

I am writing to express my concern about the Committee's current stance on Spinal Cord Stimulation (SCS) as not covered. As a physician who specializes in pain management, I have seen firsthand the benefits of SCS for my patients with chronic back and neck pain. SCS has been shown to be a safe and effective treatment for a variety of chronic pain conditions.

The current draft report relies on an imperfect analysis – through the lack inclusion of some of the highest level RCTs due to lack of conservative medical management comparator despite 2-year durability outcomes. Additionally, none of the durability data from the long-term safety and efficacy from RCTs is being considered in the current report.

The Committee's decision to not cover SCS has a significant impact on patient care. Many of my patients who are eligible for SCS are unable to afford the procedure out-of-pocket. This means that they are forced to continue living with chronic pain and the associated disability.

The Committee's decision also creates a disparity between Washington patients and patients in other states. **All other States cover SCS for chronic pain patients**. This means that Washington patients are at a disadvantage when it comes to accessing effective pain management.

The lack of access to SCS can have a devastating impact on patients' lives. Many of my patients with chronic pain are unable to work, exercise, or participate in social activities. They often experience depression and anxiety.

The Committee's decision to not cover SCS is not only harmful to patients but could have long term socioeconomic impacts on patients. SCS can help to reduce the need for opioids and other pain medications, which can save the healthcare system money in the long run.

SCS can also help to reduce the need for opioids and other pain medications. I would like to add that the lack of access to SCS can lead to increased reliance on opioids for pain management. This is a serious concern, as the opioid epidemic has claimed the lives of hundreds of thousands of Americans in recent years.

I urge the Committee to reconsider its decision and cover SCS for chronic pain patients. It is the right thing to do for our patients and for our community.

Sincerely,

Allen Shoham, MD

Apex Spine Institute

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Re: My comments on the evidence report on Spinal Cord Stimulation - Review (Jiang Wu)
Date: Sunday, October 1, 2023 3:55:58 PM
Attachments: Letter to Washington State Health Care Authority (Wu Jiang - 9-30-23).docx

External Email

Hi,

Attached is my letter to Washington State's Health Care Authority Re: The insurance coverage for Spinal Cord Stimulation therapy in the treatment of debilitating and refractory chronic pain conditions.

With this letter, I would like to comment that "***Information in this report is not a substitute for sound clinical judgment***" and the clinicians' perspective and clinical experience on SCS should also be weighed in by "***integrating this report with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability***" Furthermore, **Washington State can't be an outliner and continue denying the patients access to this potentially life-altering therapy regardless of the insurance coverage in all other states of the U.S**. The key to this discussion is **about how to prevent the overuse and abuse of this modality**.

Thanks for your time and attentions, and please confirm that the letter has been received as part of the public comments.
All the best,

Jiang Wu MD
UWMC - Center for Pain Relief

Letter to Washington State's Health Care Authority

Re: The insurance coverage for Spinal Cord Stimulation therapy in the treatment of debilitating and refractory chronic pain conditions.

To: Washington State's Health Care Authority

From: Jiang Wu MD - University of Washington Medical Center

Date: 9/30/2023

To Whom it may concern,

The Washington State's Health Care Authority is re-reviewing the scientific evidence of contemporary Spinal Cord Stimulation (SCS) Therapy before deciding on its insurance coverage for treating the debilitating and refractory chronic pain conditions for Washingtonians. As an academic pain physician at the University of Washington Medical Center, I got a chance to review the Draft Evidence Report published on September 1st, 2023, and created by Aggregate Analytics, Inc.

There is one important flaw in this report that I would like to bring to your attention - this report is produced by an external group "Aggregate Analytic, Inc." and based on the statistical analysis of limitedly available data. The authors of this report are comprised of NO clinicians, NO physicians, and NO persons with personal clinical knowledge of SCS. Therefore, the conclusion of this report is potentially incomplete and biased. "***Information in this report is not a substitute for sound clinical judgment***" as it states. When such an important decision on SCS insurance coverage is being made, I will strongly recommend that the clinicians' perspective and clinical experience on SCS should also be weighed in by "***integrating this information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability***". Positive clinical experiences have been reported in the research literature. Just to share a few reviews (1-3) listed below for your reference:

Based on additional evidence on technical advances related to the use of SCSs since 2010, it is important to systematically review, critically appraise, analyze, and synthesize research evidence evaluating the effectiveness and safety of SCS for the treatment of certain chronic pain conditions. At the same time, **Washington State can't be an outliner and continue denying the patients access to this potentially life-altering therapy regardless of the insurance coverage in all other states of the U.S**. The key to this discussion is **about how to prevent the overuse and abuse of this modality**.

During my daily chronic pain practice at the tertiary pain referral center – UWMC Center for Pain Relief, I encountered some of the most challenging and difficult-to-treat pain conditions, where all the

conservative medical and invasive surgical management failed and the SCS is their last hope. I strongly advocate the SCS as the potential option on their tables, but following the vigorous screening process to ensure its favorable risk/benefit ratio and interventional outcomes as listed under Medicare and representative private insurer coverage policies:

1. The selection of patients for implantation of spinal cord stimulators is critical to the success of this therapy.
2. The SCS's indications are limited to Failed Back Surgical Pain (FBSP) syndrome, Painful diabetic neuropathy (PDN), and Complex Regional Pain Syndrome (CRPS).
3. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain.
4. With respect to item a, 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.
5. Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team before implantation. (Such screening must include psychological, as well as physical evaluation).
6. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy item c) must be available; and
7. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.
8. Documentation of the history and careful screening must be available in the patient chart if requested.
9. Patients being selected for a trial must not have active substance abuse issues.
10. Must undergo proper patient education, discussion, and disclosure including an extensive discussion of the risks and benefits of this therapy.

With the above vigorous screening process, in only a few well-indicated pain conditions, I believe that Washingtonians will benefit from this modern and life-altering treatment just like many patients in other parts of the U.S, with favorable risk-benefit ratio and cost-effectiveness.

Thank you for your time and consideration!

Best Regards,

Jiang Wu MD

Associate Professor in the Department of Anesthesiology and Pain Medicine

University of Washington Medical Center

Center for Pain Relief

[redacted]

[redacted]

References:

1. The review of clinical evidence authored by Al-Kaisy et al (2020) examines published clinical data regarding the efficacy of 10 kHz SCS for decreasing chronic pain in patients and its potential to reduce or eliminate opioid usage. Multiple prospective and retrospective studies in patients with intractable pain demonstrated that 10 kHz SCS treatment provided ≥50% pain relief in >70% patients after at least 1 year of treatment. Pain relief with 10 kHz SCS therapy ranged from 54% to 87% in the studies. More importantly, the mean daily dose of opioids required by patients in these studies was reduced after 10 kHz SCS treatment, and on average over 60% patients in studies either reduced or eliminated opioids at the last follow-up.

Al-Kaisy, A., Van Buyten, J., Amirdelfan, K., Gliner, B., Caraway, D., Subbaroyan, J., Rotte, A., & Kapural, L. (2020). Opioid-sparing effects of 10 kHz spinal cord stimulation: a review of clinical evidence. Annals of the New York Academy of Sciences, 1462(1), 53–64. https://doi.org/10.1111/nyas.14236

2. A Comprehensive Outcome-Specific Review of the Use of Spinal Cord Stimulation for Complex Regional Pain Syndrome authored by Visnjevac et al (2017) concluded that Spinal cord stimulation remains a favorable and effective modality for treating CRPS with high-level evidence (1B+) supporting its role in improving CRPS patients' perceived pain relief, pain score, and quality of life.

Visnjevac O, Costandi S, Patel BA, Azer G, Agarwal P, Bolash R, Mekhail NA. A Comprehensive Outcome-Specific Review of the Use of Spinal Cord Stimulation for Complex Regional Pain Syndrome. Pain Pract. 2017 Apr;17(4):533-545. doi: 10.1111/papr.12513. Epub 2016 Oct 14. PMID: 27739179.

3. A Spinal Cord Stimulation Service Review from a Single Centre Using a Single Manufacturer Over a 7.5 Year Follow-Up Period, authored by Thompson et al (2017) concluded that patients with neuropathic pain undertaking SCS experience long-term reductions in pain intensity and increases in health utility and associated QALY gains.

Thomson, S. J., Kruglov, D., & Duarte, R. V. (2017). A Spinal Cord Stimulation Service Review from a Single Centre Using a Single Manufacturer Over a 7.5 Year Follow-Up Period. Neuromodulation (Malden, Mass.), 20(6), 589–599. https://doi.org/10.1111/ner.12587

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS Draft Evidence Report Comments
Date: Monday, October 2, 2023 3:39:01 PM
Attachments: image001.png
Providence comment Letter - spinal cord stimulation draft evidence report.pdf

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External Email

Good afternoon,

Please see attached comments from Providence Health in response to the draft evidence report. Please let me know if you have any questions.

Best,
Teddi

Teddi McGuire
Program Manager, Government Affairs, WA
Providence
[redacted]
Pronouns: she, her, hers

Providence

Providence Health & Services
Valley Office Park
[redacted]

October 2, 2023

Health Technology Clinical Committee
Washington Health Care Authority
Submitted via email: shtap@hca.wa.gov

RE: Spinal cord stimulation rereview

Dear Health Technology Clinical Committee Members:

On behalf of Providence Health and Services, we appreciate the committee agreeing to review the Washington State Health Care Authority's coverage determination regarding spinal cord stimulation for the treatment of refractory pain conditions. The comments below are submitted on behalf of the Providence Neuroscience Institute, including the collective feedback of our board-certified pain medicine physicians devoted to the day-to-day care of patients suffering from chronic pain in Washington State in response to the Draft Evidence Report prepared by Aggregate Analytics.

We urge the committee to incorporate the bedside clinical expertise we provide in conjunction with a comprehensive and updated review of the literature as you consider evidence of safety, efficacy, and cost-effectiveness.

Providence is a not-for-profit Catholic health care ministry committed to providing for the needs of the communities it serves – especially for those who are poor and vulnerable. In Washington state, Providence and our secular affiliated partners – Swedish Health Services, Pacific Medical Centers and Kadlec – comprise 15 hospitals, physician clinics, senior services, supportive housing, hospice and home health programs, care centers and diverse community services. In 2022, Providence and our partners provided $839 million in community benefit, including $575 million in unfunded costs of Medicaid and other government programs and $117 million in free and discounted care for Washingtonians who could not afford to pay. Together, we are working to improve quality, increase access and reduce the cost of care in all the communities we serve.

Neurostimulation is a vast and rapidly evolving treatment modality for refractory pain conditions. Pain is a symptom which does not always point to specific tissue injury. It is this very nature which makes it difficult to study and assess outcomes. As Dr. John Loeser reminds us, the concept of acute versus chronic pain may be misleading and a more accurate description would be peripherally driven or centrally maintained (Loeser JD. A new way of thinking about pain. *Pain Manag*; 2019; 9(1): 5-7). While multidisciplinary approaches, have strong support for treating pain using a biopsychosocial model there is a subgroup of patients who have a clearcut dysfunction of the central nervous system. It is these patients who have had persisting structural neural dysfunction who appear to benefit most from neurostimulation. Additionally, spinal cord stimulation (SCS) can be used as one "tool" in a patient's "toolbox" to help them improve their

ability to decrease pain and improve psychosocial function. In our comprehensive pain center at Providence Swedish, SCS is commonly used along with other evidence-based behavioral health interventions, physical and occupational therapies, exercise, movement-based therapies, pain education, and medication management to synergistically provide individualized patient-centered care.

The current policy denying coverage of SCS creates significant inequities in access to medical care for our state's population. In particular, this determination denies access to government employees, state police, firefighters, economically disadvantaged and injured workers. We encourage the committee to do a thorough, public reevaluation incorporating medical evidence, expert clinical experience, patient experience and community accepted standard of care.

Neurostimulation has demonstrated significant clinical improvement in pain, quality of life, and function in carefully selected populations. SCS is now an FDA approved treatment for Failed Back Syndrome, post-laminectomy syndrome, Complex Regional Pain Syndrome (CRPS), low back and leg pain, and diabetic peripheral neuropathy. We believe this treatment is indicated on-label in carefully selected patients as part of a patient centered treatment plan. Recently, a Cochrane review (Spinal cord stimulation for low back pain. *Cochrane Database of Systematic Reviews* 2023, Issue 3. Art. No.: CD014789.) concluded that spinal cord stimulation was not effective for low back pain. While this review had methodologic flaws in its inclusion criteria which we believe lead to a faulty analysis, we agree that SCS for the treatment of low back pain is not the most effective use of this technology. However, the rational for on label use of SCS technology focuses on failed back surgery syndrome, complex regional pain syndrome and diabetic neuropathy. These are far more specific and clear pain diagnosis that justify use.

Interestingly this year, another systematic review and meta-analysis looking at the same data came to a far different conclusion suggesting improvement in physical function after SCS therapy (El Saban, et al. Reg Anesth Pain Med 2023; 48:302-311). The El Saban analysis includes many seminal studies that were wrongly excluded in the Cochrane review which explains in part the significant difference in findings. Given that two different meta-analyses are coming to contradictory conclusions, we caution the committee against relying simply on the conclusion of meta-analysis data to support or refute the use of this technology and to dive more deeply into the data and rich clinical experience that our region offers.

At the last complete review in 2010 by the HTCC, the committee considered four key factors in developing a coverage determination for spinal cord stimulation (SCS): (1) Evidence availability and technology features, (2) Is the technology safe, (3) Is the technology effective, (4) Special populations, (5) Is the technology cost effective. Over a decade has lapsed since the last review and significant technological advances have occurred. We are writing this letter in support of a complete and balanced assessment of this technology, one that is inclusive of expert opinion as well as a comprehensive literature review.

Since a subsequent 2018 literature review by the HTCC there is increasing evidence demonstrating efficacy. We want to draw particular attention to two recent prospective randomized controlled studies published in high impact journals. In 2021, Peterson et al published in *JAMA Neurology* demonstrates spinal cord stimulation (SCS) can improve pain outcomes, quality of life, and neurological symptoms compared to medical therapy. The second study to note is Mekhail et al. published in 2020 in Lancet Neurology demonstrating SCS can improve pain outcomes for patients. Additional randomized controlled studies support SCS for

failed back surgical syndrome (Rigoard et al. 2019), post-surgical cervical chronic pain (Amirdelfan et al 2019) nonsurgical back and leg pain (Kapural et al. 2022), non-surgical intractable lumbar radiculopathy HIDENS study (Mehta et al. 2022), as well as neuropathic upper extremity pain (Canos-Verdecho et al 2021) Further studies demonstrate higher odds ratio of returning to work, improved psychological health and opioid reduction. Recently, *JAMA* published an article suggesting that burst stimulation vs placebo did not show significant difference in disability however we have serious concerns regarding the randomization and study parameters which we believe warrant closer evaluation and public discussion (Hara et al. 2022)

Similarly, the latest studies in larger patient populations demonstrate safety. A study published in *JAMA* for painful diabetic neuropathy, despite a high-risk population, demonstrated a 5% risk of surgical wound related complications (e.g. infection, wound dehiscence). The explant or removal rate was 2% and there were no patients that experienced a neurological deficit related to therapy. In the Lancet Neurology study, lead migration was the most common adverse event at 7%. The study by D'Souza etc. al highlights complications related to spinal cord stimulation to add granularity to clinical care but concluded that complications were low. Some data suggests, the rate of adverse events from SCS may be lower than rare, but severe adverse events attributed to pharmacologic therapies, including chronic opioid therapy, such as dependence and addiction.

During the 2018 literature review, the committee agreed the overall value of the SCS implant could not be ascertained. While the initial up-front cost of the spinal cord stimulator trial and implant is expensive, there is a growing body of evidence suggesting a significant improvement in quality-adjusted life years (QALY), willingness-to-pay thresholds for nationalized health care systems, and the EuroQoL-5D (EQ-5D) when compared to conventional medical management. Importantly, opioid use was observed to fall in patients treated successfully with SCS. There are at least 10 other high-quality studies that directly measure or model cost effectiveness for this therapy including assessment of different etiologies for painful conditions (see references below).

Evidence reviews give important insight into the efficacy and safety of medical treatments. However, they belie the clinical reality that physicians and patients face each day in treating painful conditions. The challenge is that even the best available evidence in this field may appear insufficient and lead to erroneous conclusions when clinical acumen of expert physicians is ignored. We bring a vast array of clinical experience to bear in treating patients with neurostimulation. Medicare and most other commercial carriers currently cover neurostimulation, and we have countless patients who have had successful improvement in pain and function. Furthermore, we are actively engaged in research devoted to promoting understanding how neurostimulation improves our patients' pain, function and well-being.

We would like to address key flaws to the report prepared by Aggregate Analytics. Spinal cord stimulation research is highly active and continues to accelerate. The number of publications since the last signals review gives some insight into the breadth of inquiry. On ES-5 the document grants RCTs as "high" strength of evidence (SOE). The authors then can choose to downgrade based upon 5 listed domains. It is important to highlight, RCTs failed to be included the analysis withstanding, despite >10 RCTs, thousands of patients in these trials, there is not a single rating of "high strength of evidence". Most importantly it is not clear why each of these studies have been downgraded. Page ES-19highlights possible reasons including implications

from a spinal cord stimulation washout period, considerations on the type of stimulation and the ability for adequate blinding. Although these points are matters for clinical debate, these are clinical questions requiring clinical expertise. The criticisms of Evidence Based Medicine are rife with concerns of drawing policy decisions based solely on statistical models while discounting clinical expertise as to which studies reflect current evidence based clinical practice of neuromodulation.

Importantly the signals update fails to include top tier published seminal work that was published in the last three years with no indication as to why. The document fails to include a key randomized controlled study published in *Lancet Neurology* by Mekhail etc. al demonstrating efficacy of closed loop stimulation in the treatment of intractable back and leg pain. Adverse events were documented at low rates in line with previous high-quality studies. Most importantly the study was published in a high impact journal for the reasons of highlighting the evolving sophistication of spinal cord stimulator treatment. Pain specialists at the moment are concerned not about if, but how best spinal cord stimulation benefits patients. The studies published by Amirdelfan et al 2019, and Mekhail etc al 2022 that enhanced our understanding for efficacy of SCS for post-surgical cervical spine and intractable non-surgical pain were also not included. Most importantly, the purpose of clinical studies is to understand if a treatment is safe and efficacious and how certain we are that these results approximate the reality for patients. We implore the committee to consider that a seemingly objective "strength of evidence" assessment must take into account what we are trying to treat, which in this case is a first-person phenomenological experience of pain and suffering. Unlike a biochemical endpoint or a physiological measurement, we must trust and rely upon the reports given by our patients. We understand that due to this unique quality in pain medicine a strength of evidence appraisal traditionally used to study a stain or blood pressure pill is difficult to apply. We urge the health care authority to recognize this limitation. We believe this limitation also lies at the heart of the draft evidence report.

Instead, we ask that the HTCC consider the recent high quality randomized controlled studies published in high impact journals for guidance eg. JAMA, Lancet Neurology. These studies give us the best possible chance of understanding the impact of spinal cord stimulation on the improvement of patient lives.

Looking forward to the future of pain research, as medicine has become more facile with collecting and interpreting more robust patient reported outcomes, we anticipate we may be able to gain more valuable insight into our patient's experiences and make better determinations regarding outcomes. The Patient-Reported Outcomes Measurement System (PROMIS) an NIH-funded initiative to develop and validate PROs for clinical research and practice is a powerful tool that we are actively implementing into our clinics. PROMIS and other outcomes we track will provide more measurable outcomes and help shape improved patient-centered care. For now, we urge the committee to review the studies and outcomes data carefully, with an understanding of the limitations of the relatively subjective outcomes that are simply the nature of treating patients suffering from chronic pain.

Our teams at Providence Health and Providence Swedish, including pain management physicians, therapists, and behavioral health specialists, are happy to collaborate and assist in any manner with the committee in reviewing the literature and merits of this evolving technology for treating patients suffering with persistent, and many times, life changing chronic pain. We look forward to the comment process and critical evaluation of the commissioned review.

Sincerely,

Lauren Platt McDonald
Executive Director, State Government Relations
Providence

Steven P. Stanos, DO, Medical Director
James R. Babington, MD
Wilson Chang, MD
Christopher Merifield, MD
Fangfang Xing, MD
Cong Yu, MD
William Kuhn, MD

References:

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May 2, 2023

RE: Washington State Health Care Authority draft key questions for Spinal Cord Stimulation

Dear Director Birch,

We appreciate the opportunity to comment on the draft key questions proposed by the Washington Health Technology Assessment Program (HTAP). We believe that an update of the Health Technology Assessment (HTA) on spinal cord stimulation (SCS) would be a valuable endeavour.

The multifaceted nature of chronic pain requires interdisciplinary assessment and multimodal treatment. First line treatment strategies are generally conservative treatments including: exercise programs, physical therapy (PT), occupational therapy, cognitive behavioural therapy (CBT), biofeedback, acupuncture, transcutaneous electrical nerve stimulation (TENS), and oral medications. Second line treatments become more intensive and involve the use of more extreme CBT and interventional techniques such as nerve blocks (local anaesthetic or steroids) and spinal injections. They can also include more powerful medications such as systemic opioids. The last line of treatment involves more advanced therapies that require surgical interventions. Systems such as intrathecal drug delivery (IDD) or spinal cord stimulators may be implanted. Surgery to repair an anatomical issue responsible for the pain should be performed prior to an SCS trial. Finally, surgical techniques that block pathways to the brain such as cordotomy, rhizotomy, and thalamotomy may be used rarely in extreme cases.

The risk profile for SCS therapy has advantages compared to surgical revision and neuroablation as it is reversible and the device may be surgically removed. Furthermore, it is common practice for patients to undergo a trial period with SCS, whereby implanted leads are connected to an external pulse generator prior to undergoing the permanent implant. During the trial stimulation period (typically 3 – 7 days, up to 30 days), tolerability (e.g., of the stimulation sensation or the device) and the degree of pain relief is assessed. If the trial stimulation is successful, lead(s) and a pulse generator are permanently implanted. The Neuromodulation Foundation recommends that an SCS trial precede major reconstructive procedures and ablative therapies [1]. In addition, SCS therapy has the advantage of having no drug side effects, including respiratory distress, as compared to IDD systems. There is consensus among international medical societies to recommend SCS as a treatment option

in patients with chronic, severe pain for which conservative treatment modalities have failed or are contraindicated [1–8]. SCS may be delivered in parallel with other therapies and should be used as part of an overall multimodal treatment strategy.

The draft PICOTS Scope presented in Table 1 of the call for public comment by the Washington State Health Care Authority would exclude recent randomized controlled trial (RCT) evidence on the use of SCS. Historical RCTs of SCS have compared SCS to conventional medical management (CMM; first- and second-line treatments detailed above), which was the standard of care at the time of the studies. Once superiority of SCS was observed versus CMM and SCS approvals were obtained for an indication (e.g., persistent spinal pain syndrome type [PSPS-T2], previously referred to as failed back surgery syndrome [FBSS]), the new standard of care became the SCS available at the time of approval. Trials of new stimulation paradigms have therefore used open-loop / fixed-output, low-frequency SCS as the comparator arm [9–14]. This comparative trial evidence, some of which is up to 24-month follow-up, should not be disregarded. SCS has only recently received FDA approval for the peripheral diabetic neuropathy (PDN) indication, hence why the comparator in the SENZA-PDN study was usual care despite the previous trials by De Vos et al. [15] and Slangen et al [16].

We would like to highlight that chronic pain patients are considered for SCS if their pain is refractory to CMM. As such, a comparison of SCS with CMM for a patient population that have already failed other treatment options may not be useful to inform decision-making. 2010 was your last literature search and much has changed in SCS. Saluda Medical conducted the first double-blind RCT which has 24 months published results, with the 36-month publication pending. This study shows SCS patients received superior pain reduction, zero explants due to lack of efficacy. Patients treated with The Evoke® SCS System can drive and operate heavy machinery all while receiving therapy.

A list of RCT evidence that compared SCS with CMM or other neurostimulation interventions is presented in Appendix A and a list of recent systematic reviews of economic evaluations of SCS is presented in Appendix B.

Yours sincerely,

Todd Davis

Todd Davis
Senior Director, Market Access & Reimbursement Strategy
Saluda Medical

[redacted]

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Appendix A. Randomized controlled trials of SCS since 2010

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Appendix B. Systematic reviews of economic evaluations of SCS since 2010

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Spinal cord stimulation
Date: Sunday, October 1, 2023 7:42:48 PM

External Email

Washington Health Care Authority
Attn: Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
Re: Draft HTA Report for Spinal Cord Stimulation (SCS)
Dear HTA Review Committee:

I am a followship trained pain management specialist working in Yakima. I believe our lead physician has already written on behalf of our group of four providers. This modality of care is essential in order to offer the full scope of services to our community. It is absurd to prevent qualified patients from nationally well-established standards of care. Withholding care has singled out a large portion of our population; care that most other insured residents in our state have access to. Living in a progressive state only contrasts how highly regressive this policy has become considering the population that it affects the most.

The Committee's decision to not cover SCS has a significant impact on patient care. Many of my patients who are eligible for SCS are unable to afford the procedure out-of-pocket. This means that they are forced to continue living with chronic pain and the associated disability.

The Committee's decision also creates a disparity between Washington patients and patients in other states. All other States cover SCS for chronic pain patients. This means that Washington patients are at a disadvantage when it comes to accessing effective pain management.

The lack of access to SCS can have a devastating impact on patients' lives. Many of my patients with chronic pain are unable to work, exercise, or participate in social activities. They often experience depression and anxiety.

The current draft report relies on an imperfect analysis – through the lack inclusion of some of the highest level RCTs due to lack of conservative medical management comparator despite 2-year durability outcomes. Additionally, none of the durability data from the long-term safety and efficacy from RCTs is being considered in the current report.

We all understand the impact opioids have made in our state, and I believe having this key option can play a prominent role in allowing patients to explore other options. The Committee's decision to not cover SCS is not only harmful to patients but could have long term socioeconomic impacts on patients. SCS can help to reduce the need for opioids and other pain medications, which can save the healthcare system money in the long run.

SCS can also help to reduce the need for opioids and other pain medications. I would like to add that the lack of access to SCS can lead to increased reliance on opioids for pain management. This is a serious concern, as the opioid epidemic has claimed the lives of hundreds of thousands of Americans in recent years.

I urge the Committee to reconsider its decision and cover SCS for chronic pain patients. Until the Committee can demonstrate otherwise, talk of equality and inclusion in medicine is just that: talk.

Sincerely,
Joe Y. Kim, MD

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: UW Medicine Comment Letter on HCA Draft Evidence Report concerning Spinal Cord Stimulation
Date: Monday, October 2, 2023 4:26:53 PM
Attachments: image001.png
UW Medicine Comment Letter to HCA 10.2.23 Spinal Cord Stimulation.pdf

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External Email

Please find attached UW Medicine's comment letter on the HCA's draft evidence report concerning spinal cord stimulation and insurance coverage.

Please let me know if you have any questions or concerns.

Sincerely,

Ian Goodhew

Ian M. Goodhew

Sr. Director of External Affairs, Associate VP | UW Medicine
[redacted]

October 2, 2023

Sue Birch, MBA, BSN, RN Director
Washington State Health Care Authority Cherry Street Plaza
626 8th Avenue SE
Olympia, Washington 98501

And via email: shtap@hca.wa.gov

UW Medicine Comments on Washington State Healthcare Authority (HCA) Draft Evidence Report on Spinal Cord Simulation (SCS)

Dear Director Birch,

On behalf of UW Medicine, we greatly appreciate the opportunity to submit written comments addressing the Washington State Health Care Authority's (HCA) September 1, 2023, Draft Evidence Report on Spinal Cord Simulation (SCS) Rereview (hereafter, "Draft Rereview").

As you well know, this draft report was prepared by the contractor Aggregate Analytics, Inc (AAI). The original WSHCA SCS Review was released July 23, 2010, and two Signal Assessment updates were released on December 29, 2014, and on August 29, 2016, respectively.

We write because we respectfully disagree with the choice of evidence reviewed that strongly impacted the conclusions to the four key questions addressed by the Draft Rereview. We are concerned about the impact that the lack of access to this valuable technology will have on our patients at UW Medicine and the 2.5 million Washingtonians with HCA-connected healthcare.

Although we recognize that the AAI team has methodological expertise in technology assessment and epidemiology, we must point to their own conclusion that "information in this report is not a substitute for sound clinical judgment."

Specifically, three of the studies that receive prominent attention in the Rereview because of their sham/placebo-controlled design have flaws in the details that make them inappropriate for analysis and

not applicable to Washingtonians. These flaws may not have been evident to those without clinical knowledge of spinal cord stimulation. The design of the Draft Rereview excludes letters to the editor, editorials, and the authors' responses which would have shed light on issues with these studies(1-6). Such discourse illuminates strengths and weakness of studies that might otherwise be missed. The three studies are as follows:

- Hara, et al.(7) is a sham-controlled crossover trial. Unfortunately, the SCS treatment provided is a specific pattern of stimulation with no evidence of efficacy, recently shown to be equivalent to sham(8). This study is in effect a comparison of sham to placebo and does not warrant inclusion in the analysis.

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Who receives SCS?

SCS is reserved for patients with high-impact pain – chronic pain that restricts function and impacts quality of life(11). The CDC estimates that 6.9% of Americans have high-impact pain and that those with incomes below the federal poverty level and/or disabilities have marked increased risk of such severe pain(12). Additionally, conditions treated by SCS including chronic back pain and painful diabetic peripheral neuropathy (pDPN) have significant racial and socioeconomic disparities(13, 14). This means that high-impact pain is over-represented in those who receive insurance via the WSHCA. These patients have limited SCS access compared to better insured Washingtonians, exacerbating racial and socioeconomic disparities for SCS(15).

SCS at UW Medicine:

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Our opinion is that the AAI Draft Rereview is significantly flawed, and it should not be accepted nor acted upon by the HCA. We believe that doing so would sully the reputation of the WSHCA as a robust, disciplined, and clear-thinking policy development organization. Regrettably, we must recommend that you reject the Draft Rereview at your upcoming meeting and immediately initiate a process of creating a new report that welcomes sound clinical judgement and addresses the issues outlined in this letter. We welcome the opportunity to engage with you in such a process.

Department of Anesthesiology & Pain Medicine

[redacted]

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University of Washington

G. Burkhard Mackensen, MD, PhD, FASE, FSCAI
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[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: I apologize if this is a duplicate SCS letter, just want to assure it is sent and received.
Date: Monday, October 2, 2023 4:18:42 PM
Attachments: image001.png
UW Medicine Comment Letter to HCA 10.2.23 Spinal Cord Stimulation.pdf

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External Email

Thank you,

Brett R. Stacey, MD

Professor, Anesthesiology & Pain Medicine
Division Chief, Pain Medicine | UW Medicine
[redacted]

Administrative Assistant: Colin M. Laughney
[redacted]

UW Medicine

UW Medicine

October 2, 2023

Sue Birch, MBA, BSN, RN Director
Washington State Health Care Authority Cherry Street Plaza
626 8th Avenue SE
Olympia, Washington 98501

And via email: shtap@hca.wa.gov

UW Medicine Comments on Washington State Healthcare Authority (HCA) Draft Evidence Report on Spinal Cord Simulation (SCS)

Dear Director Birch,

On behalf of UW Medicine, we greatly appreciate the opportunity to submit written comments addressing the Washington State Health Care Authority's (HCA) September 1, 2023, Draft Evidence Report on Spinal Cord Simulation (SCS) Rereview (hereafter, "Draft Rereview").

As you well know, this draft report was prepared by the contractor Aggregate Analytics, Inc (AAI). The original WSHCA SCS Review was released July 23, 2010, and two Signal Assessment updates were released on December 29, 2014, and on August 29, 2016, respectively.

We write because we respectfully disagree with the choice of evidence reviewed that strongly impacted the conclusions to the four key questions addressed by the Draft Rereview. We are concerned about the impact that the lack of access to this valuable technology will have on our patients at UW Medicine and the 2.5 million Washingtonians with HCA-connected healthcare.

Although we recognize that the AAI team has methodological expertise in technology assessment and epidemiology, we must point to their own conclusion that "information in this report is not a substitute for sound clinical judgment."

Specifically, three of the studies that receive prominent attention in the Rereview because of their sham/placebo-controlled design have flaws in the details that make them inappropriate for analysis and

not applicable to Washingtonians. These flaws may not have been evident to those without clinical knowledge of spinal cord stimulation. The design of the Draft Rereview excludes letters to the editor, editorials, and the authors' responses which would have shed light on issues with these studies(1-6). Such discourse illuminates strengths and weakness of studies that might otherwise be missed. The three studies are as follows:

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Medtronic Comments - SCS HTA Draft Report
Date: Friday, September 29, 2023 11:30:57 AM
Attachments: image001.png
MDT_WA State HTA SCS Comments_Sep 2023 Submission.pdf

External Email

Dear Director Birch and the Washington Health Care Authority HTCC,

Please see attached Medtronic's comments on the draft SCS HTA report. We appreciate the opportunity for input.

Regards,
Christine Ricker, Wendy Chan, and Dr. Ashwini Sharan

Christine Ricker
Economics & Reimbursement
[redacted]
Medtronic
Engineering the extraordinary

Medtronic

October 2, 2023

Via online submission at: shtap@hca.wa.gov

RE: Washington Health Care Authority- 2023 Draft Report: Spinal Cord Stimulation

Dear Director Birch,

Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to provide high-quality products and innovative therapies that improve the health outcome for all patients. Specifically, with our spinal cord stimulation therapy, we provide relief to patients who suffer from chronic pain as a treatment option when multiple first line therapies have failed. SCS demonstrates an improvement in quality of life and provides a treatment option to address the unprecedented opioid crisis in this country. Approximately 9.5 million Americans are misusing opioids with 65 percent doing so to relieve physical pain.[1] Further, an estimated 25 percent of chronic pain patients are misusing prescription oral opioids.[2]

We appreciate the opportunity to provide comment on the draft HTA report on spinal cord stimulation (SCS). While we recognize the amount of work that went into this latest report, we strongly object with the final evidence set and recommendations included for the Health Technology Clinical Committee (HTCC) review. We provide our rationale for these objections specifically in the following areas:

- Omission of several large contemporary trials relevant to addressing the key questions of the assessment
- Lack of recognition of other global HTA reviews of SCS and limited / incomplete assessment of US payer policies
- Silence and likely bias concerning historic WA state specific evidence from 2004

Ultimately, we fear that the evidence summary reflected in this report will not provide the HTCC with an unbiased view of the benefits of a technology that is covered in every other state Medicaid program in the US.

It is important to note that spinal cord stimulation is often a last resort for patients living with chronic pain and is only recommended by most national and regional payers when patients have tried and failed multiple conservative medical management (CMM) treatment options. Virtually all coverage policies include specific criteria for coverage including a patient must

[1] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56).
https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf. Accessed April 2022.

[2] Vowles KE, McEntee ML, Julnes PS, et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain. 2015;156(4):569-576.

pass a trial/evaluation period demonstrating pain improvement of 50% or more prior to qualifying for the permanent implant. In 2021, CMS started requiring prior-authorization review of SCS procedures to further ensure appropriate utilization. Evaluating CMS Research Identifiable Claims data for patients with Medicare fee-for-service coverage in the state of WA, an average of 632 SCS permanent implant procedures were performed per year over the last five years (ranging from 538 in 2016 to 651 in 2021) by physicians practicing in the state.[3] Therefore, utilization is appropriately managed and SCS is only reserved for the small subset of patients meeting coverage criteria.

Draft Report Comments

(1) Clinical Evidence - RCTs

We respectfully request that the committee evaluate, rather than exclude, randomized studies which compare different types/modalities of SCS. Randomized clinical trials (RCTs) evaluating SCS compared to CMM have been extensively studied and demonstrate that for certain indicated patients, SCS improves pain and functional outcomes relative to CMM. With the advancement of technology to better improve clinical outcomes, new trial designs comparing contemporary/novel SCS waveforms to historic SCS waveforms should be included. We realize that the research objective is to evaluate the efficacy of SCS vs. patients not treated with SCS; however, as the therapy technology has advanced significantly in the last decade, much of the contemporary evidence is of this study design (randomized comparison of waveforms). Evaluation of totality of the evidence would allow for a more complete picture of the technologies used in clinical practice today.

For example, the RCT by Fishman et al. compared a novel waveform, Differential Target Multiplexed (DTM) SCS to traditional SCS was excluded from the HTA due to the PICOS restrictions on trial comparators.[4] This large trial enrolled 128 patients across 12 study sites and demonstrated a low back pain responder rate (defined as a 50% or more reduction in pain versus baseline) of 83.7% with DTM SCS vs. 51.1% with traditional SCS ($p = .001$) at 12 months. Further, this study showed a greater proportion of patients treated with DTM SCS meeting the definition of a "profound responder" with an 80% or more improvement in low back pain relative to traditional SCS (69% vs. 35%). This is just one example of several well-designed randomized studies excluded from the HTA. A full list of relevant RCTs comparing "new" waveforms with associated improvements in clinical efficacy vs. "older" waveforms is listed in Appendix A.

Second, we note while relevant RCTs were excluded based on the structure of the PICOTS, a methodologically flawed RCT was included in the final assessment published by Hara et al.[5] The methods employed in the trial prompted a letter to the editor of JAMA, authored by

[3] Internal Medtronic analysis of licenced CMS RIF claims data 2016-2021.

[4] Fishman M, Cordner H, Justiz R, Provenzano D, Merrell C, Shah B, Naranjo J, Kim P, Calodney A, Carlson J, Bundschu R, Sanapati M, Mangal V, Vallejo R. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Pract. 2021 Nov;21(8):912-923.

5 Hara S, Andresen H, Solheim O, et al. Effect of Spinal Cord Burst Stimulation vs Placebo Stimulation on Disability in Patients With Chronic Radicular Pain After Lumbar Spine Surgery: A Randomized Clinical Trial. *Jama*. 2022;328(15):1506-1514.

seven pain physicians globally.[6] We deeply question the process by which study quality with GRADE assessment was applied, ranking this trial as "Good" evidence for pain and functional outcomes despite this publicly available letter to the editor by prominent clinicians in the field of pain medicine.

(2) Global HTAs and US Coverage Policies

We question the inclusion criteria applied in Tables 5 and 6 on the selection of other global HTAs and national payer coverage policies. The two HTAs summarized compared "new" waveforms, specifically closed-loop SCS and high-frequency SCS vs. "older" waveforms. However, this is precisely the RCT study designs excluded from the body of the report – so it is unclear why these HTAs were presented. We question why the original widely referenced SCS HTAs comparing traditional SCS to CMM performed in France (HAS) and the UK (NICE) were not listed.[7,8]

In the summary of national payer policies, the review cites only the CMS NCD, Aetna, and Cigna policies – however there are several more relevant payers with coverage policies available and serving patients in the state of WA including: Premera Blue Cross, UnitedHealthcare, Molina Healthcare, Regence Blue Shield, Centene Corporation, Community Health Plan of Washington, Elevance Health, Providence Health Plan, Kaiser, and Humana. Many of these companies utilize rigorous privately contracted evidence reports similar to the methods employed by the Washington Health Care Authority, including those by ECRI, HAYES, and Evidence Street; ultimately using these reports to inform a favorable coverage decision.

The HTA does not reference multiple professional society guidelines are supportive of use of SCS for specific patients, including the American Society of Interventional Pain Physicians (ASIPP), American Society of Anesthesiologists, American Pain Society, and the Neuromodulation Therapy Access Coalition).[9,10,11,12] The most recent guidelines published in 2023 by the American Society of Regional Anesthesia and Pain Medicine (ASRA) used a Delphi method to reach consensus on appropriate patient selection and trial stimulation

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[6] Eldabe S, Gilligan C, Taylor RS, Patel KV, Duarte RV. Issues in design, conduct, and conclusions of JAMA's Hara et al.'s randomized clinical trial of spinal cord burst stimulation versus placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery. Pain Pract. 2023 Mar;23(3):232-233.

[7] Haute Autorite de Sante (HAS). Assessment of spinal cord stimulation. Summary of the health technology assessment report. March 2014: URL: https://www.has-sante.fr/upload/docs/application/pdf/2014-05/short_text_spinal_cord_stimulation.pdf .

[8] NICE. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. Technology appraisal guidance TA159. 22 October 2008. https://www.nice.org.uk/guidance/ta159

[9] Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. 2013;16(2 Suppl):S49-283

[10] American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. 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(4):810-833.

[11] Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). 2009;34(10):1066-1077

[12] North R, Shipley J. Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain. Pain Med. 2007;8(s4):S200-S275

considerations for SCS therapy, further refining the considerations for appropriate patient selection to maximize the probability of a favorable patient outcome on therapy.[13]

Finally, while not strictly an HTA or coverage policy, it is important to include citation of the US Department of Health & Human Services Pain Management Best Practices Inter-Agency Task Force Report in 2019 which was omitted.[14] This report identified a key gap in pain management today are "inconsistencies and frequent delays … in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context". The agency recommended that CMS and private payers provide consistent and timely insurance coverage for evidence-informed interventional procedures; one of which listed is SCS.

(3) Historic WA State Evidence

Finally, when examining the genesis of the questions surrounding SCS efficacy - we recognize that nearly twenty years ago the agency covered SCS for patients with worker's compensation coverage with failed back surgery syndrome (FBSS) under a coverage with evidence development framework, resulting in two publications.[15,16] These were inherently flawed studies given patients were not randomized to SCS treatment versus management by a pain physician versus usual care with a non-pain specialist. Patients were instead allowed to choose their own course of treatment which introduces significant bias in meaningful treatment group comparisons, resulting in a design that arguably would not meet the GRADE criteria for a high-quality study. Additionally, the SCS treatment arm in this study included *both* patients with only a SCS trial and those progressing to a permanent implant – which is counterfactual to the rationale for a trial procedure. The technological advancements of SCS over the past two decades are proven in well-designed RCTs (Appendix A), rendering this historic data on the WA state worker's compensation population obsolete. We urge the HTCC to reconsider any bias they may have concerning the efficacy of SCS related to this historic, inaccurate, and obsolete clinical study.

Summary

We hope that given the limitations of the current draft report that the HTCC commit to the processes outlined which state that a coverage determination is made not only based on the evidence report but also considers comments such as ours and other relevant stakeholders. We strongly urge the HTCC to classify SCS a technology which has a "unique impact on a specific population based on factors such as sex, age, ethnicity, race, or disability" as listed in the clinical committee meeting and decision process. Patients covered by Medicaid, those

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[13] Shanthanna H, Eldabe S, Provenzano DA, Bouche B, Buchser E, Chadwick R, Doshi TL, Duarte R, Hunt C, Huygen FJPM, Knight J, Kohan L, North R, Rosenow J, Winfree CJ, Narouze S. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. Reg Anesth Pain Med. 2023 Jun;48(6):273-287.

[14] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

[15] Turner JA, Hollingworth W, Comstock BA, Deyo RA. Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Pain. 2010 Jan;148(1):14-25. doi: 10.1016/j.pain.2009.08.014

[16] Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: an observational study in a workers' compensation population. Spine (Phila Pa 1976). 2011 Nov 15;36(24):2076-83.

living with an injury covered by worker's compensation benefits, and public employes in local WA state health plans with chronic, intractable pain who have failed other forms of pain management can benefit through access to SCS – which is afforded to all other populations within the state today. SCS is a safe and effective late treatment option for patients who suffer from chronic pain. The technology has advanced to address clinical needs with multiple platforms to provide greater freedom for clinicians to personalize medicine unique to patients' conditions as pain is complex and variable. By being the outlier of the only state-funded payer that non-covers SCS, the Washington State Health Care Authority is providing a significant disservice to its members and clinicians considering the historical and contemporary randomized trials that continue to support the efficacy and clinical benefit of SCS.

Request

Our request is that the HTCC exercise their respective expert clinical judgement and align WA state with the rest of the country by either (1) covering SCS technology or (2) covering the technology under specific circumstances – such as limited to specific indications and/or with prior authorization review.

Thank you for the opportunity to submit comments as part of this process. If you have questions, feel free to reach out to myself ([redacted]) or my Reimbursement colleague Wendy Chan (VP Reimbursement, [redacted]).

Sincerely,

Ashwini D. Sharan, MD, MSQHS
Chief Medical Officer
Medtronic Neuromodulation
[redacted]

Appendix A. Relevant Randomized Controlled Trials *Excluded* from the Draft HTA Report

Reference	Year	Treatment Comparison
Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Yearwood TL, Bundschu R, Yang T, Benyamin R, Burgher AH. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. 2016 Nov;79(5):667-677.	2016	HF10 vs traditional SCS
Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. Neuromodulation J Int Neuromodulation Soc. 2018;21(1):56-66	2017	BURST vs traditional SCS
Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. Lancet Neurol. 2020;19(2):123-34.	2020	CL-SCS vs traditional SCS
North J, Loudermilk E, Lee A, Sachdeva H, Kaiafas D, Washabaugh E, Sheth S, Scowcroft J, Mekhail N, Lampert B, Yearwood T, Shaw E, Atallah J, McLeod C, Han J, Yu C, Sedrak M, Lucas R, Trobridge A, Hegarty J, Miller N, Chen L, Jain R. Outcomes of a Multicenter, Prospective, Crossover, Randomized Controlled Trial Evaluating Subperception Spinal Cord Stimulation at ≤1.2 kHz in Previously Implanted Subjects. Neuromodulation. 2020;23(1):102-08.	2020	Subperception vs Supraperception SCS
Breel J, Wille F, Wensing AGCL, Kallewaard JW, Pelleboer H, Zuidema X, Bürger K, de Graaf S, Hollmann MW. A Comparison of 1000 Hz to 30 Hz Spinal Cord Stimulation Strategies in Patients with Unilateral Neuropathic Leg Pain Due to Failed Back Surgery Syndrome: A Multicenter, Randomized, Double-Blinded, Crossover Clinical Study (HALO). Pain Ther. 2021 Dec;10(2):1189-1202.	2021	1000 Hz SCS vs 30 Hz SCS
Fishman M, Cordner H, Justiz R, Provenzano D, Merrell C, Shah B, Naranjo J, Kim P, Calodney A, Carlson J, Bundschu R, Sanapati M, Mangal V, Vallejo R. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Pract. 2021;21(8):912-23.	2021	DTM-SCS vs traditional SCS
Wallace MS, North JM, Phillips GM, Calodney AK, Scowcroft JA, Popat-Lewis BU, Lee JM, Washabaugh EP 3rd, Paez J, Bolash RB, Noles J, Atallah J, Shah B, Ahadian FM, Trainor DM, Chen L, Jain R. Combination therapy with simultaneous delivery of spinal cord stimulation modalities: COMBO randomized controlled trial. Pain Manag. 2023;13(3):171-184.	2023	Sub-perception and paresthesia-based SCS vs paresthesia-based SCS alone

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Draft Evidence Report on Spinal Cord Stimulation - Nevro Comment Letter
Date: Monday, October 2, 2023 3:28:01 PM
Attachments: image001.png
WA HTA Draft Report - Nevro Comment Letter_vF.pdf

External Email

Washington State Health Care Authority – please find the attached comment letter from Nevro Corporation related to the recent draft evidence report on Spinal Cord Stimulation. We appreciate the opportunity to provide feedback and look forward to our continued engagement on this matter.

If you have any questions, please do not hesitate to reach out to myself or any of my colleagues copied on this e-mail. Thank you!

Sandeep Patil
Senior Director,
Government Affairs and
Market Access
[redacted]

[redacted]

VIA Electronic Submission to Shtap@hca.wa.gov
October 2, 2023

Re: Draft Evidence Report on Spinal Cord Stimulation

Washington State Health Care Authority,

We appreciate the opportunity to submit comments to the Washington State Health Care Authority's (HCA) Draft Evidence Report on Spinal Cord Stimulation (SCS). Given the overwhelming volume of peer-reviewed clinical evidence and broad adoption of SCS by private and public payers as a safe and effective therapy for chronic pain, we are hopeful that this re-review will result in a change of coverage for SCS therapies, with reasonable, evidence-based coverage criteria. Washington (WA) remains the only State in the US that does not cover SCS for any indications. This policy change is long overdue to provide residents of WA the same level of medical care as in all other states including those with both commercial insurance and Medicare coverage. When clinically appropriate, as determined by their physicians, suffering WA residents deserve access to this demonstrated clinically safe and effective therapy.

Nevro Corporation ("Nevro") is a global medical device company focused on providing innovative products that improve the quality of life of patients suffering from debilitating chronic pain. Nevro has developed and commercialized the Senza SCS System (Senza®, Senza II™, and Senza Omnia™, Senza HFX iQ), an evidence-based, non-pharmacologic neuromodulation platform that delivers electrical stimulation for the treatment of chronic intractable pain of the trunk and/or limbs. Originally approved by the FDA in 2015 under a PMA[1], the Senza SCS System is indicated for patients suffering from one of the following:

- Failed back surgery syndrome;
- Intractable low back pain, leg pain;
- Diabetic neuropathy; and
- Non-surgical refractory back pain.

After reviewing the draft evidence report on SCS, we believe there are critical omissions, improper assessments of the quality of evidence, and a general lack of understanding for SCS as a therapy for chronic pain. Additionally, the draft report does not consider the current coverage landscape for SCS therapy, which is unusual for evidence reports commissioned by the HCA. The report in the current state would likely lead to the wrong conclusions being made by the HCA and continued failure of State-funded insurance plans by restricting access to a safe, efficacious, and non-opioid alternative for chronic pain management.

<u>Omissions from the Report:</u>
Due to issues with the construction of the Key Questions and the framework of this analysis, which Nevro issued comments on May 3, 2023, there were critical omissions from the report, specifically on high-quality Level 1 Randomized Controlled Trial (RCT) evidence. One of the studies excluded was the SENZA-RCT published by Kapural et al (2016) [2] evaluating 198 subjects with both back and leg pain randomized to 10 kHz high frequency SCS or traditional SCS. This was a "head-to-head", carefully conducted RCT with multiple outcomes measures and with treatment and control arms followed for 24 months. Among the conclusions of this study were that both high frequency SCS (HFSCS) and

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022A.pdf
[2] Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. 2016 Nov;79(5):667-677.

traditional SCS demonstrated safe and highly effective pain relief for patients with chronic pain with a superiority finding of HFSCS.

Additionally, the report excluded any long-term safety and efficacy data from multiple RCTs. This includes data from the SENZA-PDN RCT published by Petersen et al (2023)[3] evaluating 216 patients with refractory painful diabetic neuropathy with 10 kHz SCS compared to conventional medical management (CMM) and data from the SENZA-NSRBP RCT published by Kapural et al (2022)[4] evaluating 159 patients with chronic low back pain and no history of spine surgery who were refractory to CMM. The one and two-year outcomes of the treatment arm in these crossover design studies were not taken into consideration in the draft report, citing lack of comparator after the 6-month crossover option. These RCTs were designed in a pragmatic fashion, like the way many patients present to health care providers in real-world settings – not having a crossover option or forcing patients failing conventional medical management to remain with an unsatisfactory treatment for one or two years is neither ethical nor practical when considering the way treatment decisions are made for late or last resort therapies such as SCS.

Improper Assessments of the Quality of Evidence:

Many of the studies considered in the draft report were given assessments of "Low" or "Insufficient" strength of evidence. In the appendices of the report, more detail was provided on the framework for this grading system, which were applied inconsistently and inappropriately in many cases. For example, RCTs with > 10 % difference in follow-up between groups were downgraded when determining the strength of evidence. However, many of the described RCTs were randomized before the required temporary, short term clinical trial. Those that failed the trial or otherwise did not receive the intended therapy were study protocol excluded from follow-up visits and conservatively considered treatment failures for the purposes of intention to treat analyses. The most important clinical metric, consistent with actual practice, is the permanent implant subset (PIS) that were provided long term treatment. Other studies such as Hara (2022)[5] were randomized *after the* trial. Yet, the review inappropriately applies the same criteria to both study designs greatly favoring the Hara findings. In fact, if we consider Kapural (2022) versus the Hara (2022) proportion of those reported who received trials:

Kapural Subject Disposition[4]

Randomized before trial – true ITT

- 89 % - (71/80) of those trialed (ITT) at 12 M
- 93% - (64/69) of all implanted reported at 12 m
    - 89 % - (71/80) of those trialed (ITT) at 12 M
    - 93% - (64/69) of all implanted reported at 12 m
    - 100% - Detailed reasons for withdrawals and disposition *of all randomized subjects*

HARA Subject Disposition[5]

Randomized after trial

- 65% - (42/65) of those trialed at 12 m
- 84% - (42/50) of those implanted at 12 m

25% - Reason given, others just "withdrew consent"

[3] Petersen EA, Stauss TG, Scowcroft JA, et al. Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: 24-Month results of a randomized controlled trial. Diabetes Res Clin Pract. 2023 Aug 1;203:110865. doi: 10.1016/j.diabres.2023.110865.

[4] Kapural L, Jameson J, Johnson C, et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. J Neurosurg Spine. 2022 Feb 11;1-12. doi: 10.3171/2021.12.SPINE211301.

[5] Hara S, Andresen H, Solheim O, et al. Effect of Spinal Cord Burst Stimulation vs Placebo Stimulation on Disability in Patients With Chronic Radicular Pain After Lumbar Spine Surgery: A Randomized Clinical Trial. JAMA. 2022 Oct 18;328(15):1506-1514

Additionally, one of the criteria "Risk of Bias" assessments was based on if the authors were "independent". As is true across all specialties and most novel pharmaceutical trials, many of the referenced large scale RCTs and studies are funded at least in part by industry, albeit with pre-specified statistical plans, FDA audited locked data bases collected by independent personnel, independent statisticians, independent reviewers, and study monitors. However, studies such as Hara (2022) a single-center trial comparing a previously proven ineffective therapy[6] with placebo should be considered as low-quality evidence based on the many flaws in their study design which have been documented in several publications such as Durbhakula et al (2023)[7]. Traeger (2022)[8] structured their review to include only placebo-controlled, double blinded RCTs disallowing inclusion of the many comparative RCTs basing their final conclusions on only one "suitable" RCT - namely the discredited Hara (2022) trial.

Current SCS Coverage Landscape

SCS is broadly covered by insurers, both commercial and government funded. For Medicare, SCS has been covered for nearly three decades through both National and Local Coverage Determinations (LCD). Medicare coverage in the State of WA is governed by Noridian, which has LCD L36204 stating the following key coverage criteria:

- SCS may be covered as therapies for the relief of chronic pain, best suited for neuropathic pain but *may have some limited value* in other types of nociceptive severe, intractable pain.
- SCS therapy should be considered as a late option after more conservative attempts such as medications, physical therapy, psychological therapy, or other modalities have been tried.
- Patients must have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation).
- Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation.

The associated Billing and Coding Article A57792 provides details on ICD-10 Diagnoses codes that support medical necessity that include, but is not limited to, codes describing diabetic mononeuropathy, diabetic polyneuropathy, causalgia, chronic pain syndrome, chronic regional pain syndrome, spondylopathies, spondylosis, spinal stenosis, intervertebral disc disease, radiculopathy, and post laminectomy syndrome.

All major commercial health plans, regional health plans, and even most small health plans all offer some level of coverage for SCS. Of the top five commercial health plans by covered lives, the general coverage landscape is as follows:

Payer	Covered Lives	Indication		
		Painful Diabetic Neuropathy	Chronic Refractory Back Pain	Failed Back Surgery Syndrome
Premera Blue Cross	2,289,805	☑	☑	☑
UnitedHealthcare	1,029,696	☑	☑	☑

[6] Eldabe S, Duarte R, Gulve A, Williams H, Garner F, Brookes M, Madzinga G, Buchser E, Batterham AM. Analgesic Efficacy of "Burst" and Tonic (500 Hz) Spinal Cord Stimulation Patterns: A Randomized Placebo-Controlled Crossover Study. Neuromodulation. 2021 Apr;24(3):471-478.

[7] Durbhakula S, Broachwala MY, Schuster NM, McCormick ZL. Striking errors in the methodology, execution, and conclusions of the Cochrane Library review of spinal cord stimulation for low back pain by Traeger et al. Pain Med. 2023 Aug 1;24(8):923-925.

[8] Traeger AC, Gilbert SE, Harris IA, et al. Spinal cord stimulation for low back pain. Cochrane Database Syst Rev. 2023 Mar 7;3(3):CD014789.

Molina Healthcare	1,019,202	☑		
Regence BlueShield	837,051	☑	☑	☑
Kaiser Foundation Health Plan of Washington	664,473	☑	☑	☑

Legend: ☑ = Covered; = ☑ Case by Case Coverage

Many commercial health plans utilize third-party health technology assessments when making these coverage decisions. These HTAs include organizations such as Blue Cross Blue Shield Evidence Street, ECRI, and Hayes. All these organizations have done evidence assessments of spinal cord stimulation and have published reports highlighting the safety and effectiveness of the therapy for multiple indications.

The Evidence Street report, last updated in June of 2023, determined that for individuals with treatment-refractory chronic pain of the trunk or limbs who are treated with standard spinal cord stimulation, high frequency spinal cord stimulation or dorsal root ganglion stimulation "The evidence is sufficient to determine that the technology results in an improvement in the net health outcome." This analysis included many of the above cited publications that were missing from the current Washington HCA Draft Report.

Similarly, ECRI published a Clinical Evidence Assessment (CEA) on high-frequency spinal cord stimulation, the Senza SCS System, in May 2022 which concludes the evidence is somewhat favorable and that "Evidence from one systematic review (SR) with network meta-analyses and two randomized controlled trials (RCTs) shows that Senza is safe and reduces pain by more than 50% for up to one year in patients with chronic pain compared with CMM. Three additional RCTs indicate Senza reduces pain and improves quality of life (QOL) as well as or better than other SCS systems." The RCTs used to make this conclusion were the SENZA-PDN and SENZA-NSRBP data, including long-term outcomes which were not fully considered in the current Washington HCA Draft Report.

Additionally, most State Medicaid plans and Workers Compensation plans offer some type of coverage for SCS. Washington stands alone in the non-coverage decision, and the report lacking this conclusion is unusual.

For example, in the April 2020 Washington HCA Report on Vagal Nerve Stimulation (VNS) for Epilepsy and Depression, Payer Policies and clinical practice guidelines were considered when making conclusions about the safety and efficacy of the treatment. Additionally, in the evaluation of VNS therapy, the conclusions were based on significantly fewer studies than those for SCS. The types of studies evaluated included those considering various modalities of stimulation and not limited to only those comparing to CMM or "treatment as usual".

When comparing the July 2018 review of SCS to the review of VNS, the differences in conclusions based on a similar type of procedure are stark. For example, efficacy of SCS was deemed insufficient despite more studies classified as "moderate" or "good" compared to VNS. Also, efficacy was determined to be "unproven" for SCS for the lack of placebo or sham control, but not similarly applied for VNS. For safety, a procedure with a comparable level of invasiveness was deemed "less safe" for SCS but not for VNS.

It is our understanding that the Washington HCA conducts evidence reviews with a similar methodology, in a consistent and fair format – which does not seem to be the case specifically with SCS and patients in pain. The discrimination against these patients who are in debilitating chronic pain seems apparent in the draft report and results in grave concern for other options that might be considered for management of their pain – specifically initiating chronic opioid usage, which is not supported by evidence and have proven, detrimental societal impacts. The Washington State

Department of Health estimates that 17,502 Washington residents died from a drug overdose over the between 2007 and 2021. 68% of those deaths involved an opioid.

We believe the WA HTA draft report relies on inconsistent, incomplete, and inaccurate review of the available evidence. The resulting conclusions are out of line with modern medical practice across the country and, indeed, around the world. We hope the committee will come to a reasonable conclusion for evidence-based coverage of the many patients who suffer needlessly with chronic pain. Reasonable coverage would include criteria like those policies seen by other policy decision makers such as Noridian.

We appreciate the opportunity to submit comments and thank you for your consideration. We look forward to engaging in the process as you move forward with this review. Should you have any questions, please do not hesitate to contact David Caraway, MD, PhD at [redacted]. Thank you in advance for your review of our comments.

Sincerely,

David Caraway, MD, PhD
Chief Medical Officer
Nevro Corporation

VIA Electronic Submission to Shtap@hca.wa.gov
May 3, 2023

Re: Draft key question for Spinal Cord Stimulation

To Whom it May Concern,

We are pleased to submit comments to the Washington State Health Care Authority's Draft key questions – Spinal Cord Stimulation (SCS). We are hopeful that this re-review will result in a change of coverage for SCS therapies as WA is the only state and payer in the US that does not cover any form of SCS. This policy change is long overdue for the residents of WA.

Nevro Corporation ("Nevro") is a global medical device company focused on providing innovative products that improve the quality of life of patients suffering from debilitating chronic pain. Nevro has developed and commercialized the Senza SCS System (Senza®, Senza II™, and Senza Omnia™, Senza HFX iQ), an evidence-based, non-pharmacologic neuromodulation platform that delivers electrical stimulation for the treatment of chronic intractable pain of the trunk and/or limbs. Originally approved in 2015, the Senza SCS System is the only SCS system indicated for patients suffering from one of the following:

- Failed back surgery syndrome;
- Intractable low back pain, leg pain;
- Diabetic neuropathy; and
- Non-surgical refractory back pain.

The Senza SCS System delivers stimulation at low frequency (between 2 – 1,200 Hz) and high frequency (10,000 (10 kHz)), which uses 10kHz waveform to provide pain relief without inducing paresthesia. Of note, the Senza SCS system is the only system that does not induce paresthesia.

We have reviewed your draft questions and respectfully request that WA HTA consider the following additions:

- **Question 1:** We would like to request the following be added: ***What is the evidence of short and long term effectiveness safety of low frequency spinal cord stimulation compared with high frequency spinal cord stimulation?*** We would like to see this included and considered as there are peer reviewed publications and Level I long term data available. There is data available in peer reviewed publications from an RCT that compared low frequency SCS therapy in one device to other high frequency SCS in a completely different device. Payers often request comparative, head-to-head, studies of devices and including this question will be important to the evaluation.
- **Question 2:** We would like to request the following be added: What is the evidence of safety of low frequency spinal cord stimulation compared with high frequency spinal cord stimulation?
- **Patient Populations:** We would like to request that in the new review, WA HTA conduct a sub-analysis by SCS systems and their approved indications. Not all SCS devices have been evaluated for safety and efficacy, or FDA approved in the same patient populations.

We appreciate the opportunity to submit comments and thank you for your consideration. We look forward to engaging in the process as you move forward with this review. Should you have any questions, please do not hesitate to contact Sandeep Patil at [redacted] Thank you in advance for your review of our comments.

Sincerely,

David Caraway, MD, PhD
Chief Medical Officer
Nevro Corporation

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: WASHINGTON STATE HEALTH CARE AUTHORITY DRAFT ASSESSMENT
Date: Sunday, October 1, 2023 4:37:13 PM
Attachments: Washington State HCA_Reconsideration of SCS for Intractable Pain_Boston Scientific Comment Letter on HTA Draft Report_29SEP2023.pdf

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External Email

Dear Ms. Birch,

Appreciate the opportunity for stakeholder comments regarding the draft spinal stimulation considerations by the State> Please see attached letter.

Sincerely,

Nileshkumar Patel MD, MBA

BOSTON SCIENTIFIC, INC.
Neuromodulation Division

[redacted]

Boston Scientific
Advancing science for life™

September 29, 2023

Via Mail and Electronically Submitted: shtap@hca.wa.gov

Sue Birch, Director
Washington State Health Care Authority
Cherry Street Plaza, 626 8th Avenue SE
Olympia, Washington 98501

RE: WASHINGTON STATE HEALTH CARE AUTHORITY DRAFT ASSESSMENT OF SPINAL CORD STIMULATION [September 1, 2023]

Dear Ms. Birch:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Agency's coverage reconsideration for spinal cord stimulation (SCS). As one of the world's leading manufacturers of spinal cord stimulation and interventional pain management technologies, we remain committed to innovation which consistently delivers high quality patient care, outcomes favorable to the patient, care provider and broader health system. The needs and wants of all the stakeholder, including patients, practitioners and payers are carefully considered in development and deployment of our technologies, the most important driver being patient safety and clinical outcomes. With respect to outcomes, we are keen to ensure innovations are demonstrably superior to existing therapies, and there is robust clinical data from randomized controlled trials that is corroborated with real world evidence. This body of clinical evidence demonstrates improvement in pain, function, patient satisfaction and an overall decrease in healthcare utilization and opioid consumption.

Chronic pain has a profound impact on society. In recommendations published in April 2023, the United States Centers for Disease Control & Prevention (CDC) estimates 17.1 million citizens of the United States suffer from high impact chronic pain[1]. This is pain for more than three months affecting function and, activities of daily living including the ability to work and support their families. More than $635 billion in direct and indirect costs (including lost productivity at work) reflect the significant burden of this disease[2]. CDC experts also note[3] that chronic pain has a direct and significant effect upon mental health, diabetes, cardiovascular disease and cardiopulmonary disease. Chronic pain has also been linked to depression[4], Alzheimer's disease and related dementias[5], higher suicide risk[6], and substance abuse and misuse[7].

Health care resource consumption is significantly greater for chronic pain patients. Hospital admissions, emergency care and professional and diagnostic services add costs otherwise manageable when SCS is indicated[8]. Chronic pain patients account for 11%-16% of emergency room visits, with 7% of these patients visiting multiple times per year[9]. Sadly, the prevailing options for the citizens of Washington State are inadequate in controlling pain, restoring function, and returning to meaningful engagement in life. This is because the State has curtailed opioid use[10] and restricted access to FDA-approved options that have been proven cost-effective including neuromodulation.

Boston Scientific's comments focus on four key areas relevant to the Health Care Authority's evaluation of evidence and recommendations in support of coverage aligned to public policy, health technology assessment reviews, public and private payer positions and community standards of care as follows:

A. Consideration of the Body of Published Evidence

B. Accessibility To FDA-Approved Opioid Alternatives

C. SCS Cost Effectiveness

D. Equitable Access to FDA-Approved Devices

* * * * *

A. THE BODY OF PEER REVIEWED AND PUBLISHED LEVEL I-V EVIDENCE PROVES THE SAFETY AND EFFECTIVENESS OF SPINAL CORD STIMULATION FOR CHRONIC PAIN PATIENTS

Aggregate Analytics, Inc. (AAI) selectively omitted significant research and published outcomes that consistently demonstrate the safety and comparative effectiveness across multiple SCS platforms. We request consideration of the full body of evidence, including randomized controlled trials published in peer reviewed journals by leading academics. A few examples include:

1. FAST Sub-Perception Therapy

In this multi-center case series, 41 consecutive patients were evaluated under Institutional Review Board (IRB) approval. Twenty-six evaluable subjects were assessed at 3-months, and 18 subjects at 6-month post-implant. Most patients were diagnosed with failed back surgery syndrome, followed by lumbosacral radiculopathy.

Mean overall pain score at baseline was 8.4 ± 0.2 (n = 41). After activation of FAST, a 7.1-point reduction in overall pain score (1.3 ± 0.2, $p < 0.0001$) was reported within 11.2 ± 1.9 minutes (n = 34). This decrease in pain score was sustained at 3-month (1.6 ± 0.3, n = 26) and 6-month follow-up (1.7 ± 0.4, n = 18). At last follow up (mean = 223 ± 132 days), a pain score of 1.6 ± 0.3, n = 30 was reported. Researchers observed a profound, and almost immediate, response using paresthesia-free analgesia[11].

Mechanistically, FAST sub-perception therapy enables inhibition of the Aβ fibers surrounding the source of pain[12]. Synaptic activation through neurostimulation leads to inhibitory interneurons that suppress the transmission of nociceptive information relayed from the spinal circuits corresponding to the pain center.

This observational case series was unfortunately excluded by AAI, even though it would be highly relevant to communities served by the Washing State Health Care Authority. FAST offers rapid feedback from which lead placement may be confirmed and programs adjusted to meet individual requirements unique to each patient. Active patient participation in returning to work, functional objectives, mental health and medication use aligns with State objectives and is well supported by the evidence[13].

2. COMBO Randomized Controlled Trial

Published in March 2023, the COMBO randomized controlled trial results were shared by University of California San Diego professor Dr. Mark Wallace[14]. Technological advancements in SCS allow systems to be personalized to meet individual patient needs. Boston Scientific's WaveWriter Alpha™ System enables precise targeting to the source(s) of pain using conventional paresthesia-based stimulation or sub-perception therapy[15]. Researchers found additional flexibility improved already robust patient outcomes, enhancing analgesia for persistent neuropathic pain.

Having failed at least six months of conservative therapy, 89 subjects were randomized to an active group compared with the control. The average duration of low back/leg pain was 16.2 years. All subjects completed 12-week follow-up. Long-term outcomes were evaluable at one (n=79) and two years (59) following the procedure. Demographically, 65.2% (58/89) of the subjects were female, mostly diagnosed with failed back surgery syndrome (60.7%) or radiculopathy (22.5%). Average opioid medication (MME) use was 31.8 [SD: 44.14]. Average overall pain score was 7.4 and low back pain was reported as 7.6 using the validated Verbal Rating Scale (VRS). Disability was measured using the Oswestry Disability Index (ODI) for which the mean score was 54.2 [SD: 8.9] (i.e., Severe Disability).

The primary endpoint (≥50% pain reduction at 3-months with no increase in average opioid medication) was met (p<0.0001). A responder rate of 88% (36/41) was observed in cohorts receiving combination therapy, as compared to 71% (34/48) in the control group receiving traditional SCS. Both groups achieved significant reduction in disability. ODI showed a 26-point improvement for both groups compared to baseline (p<0.0001). Responder rates improved in disability and patient satisfaction remained high over the two-year duration of the study.

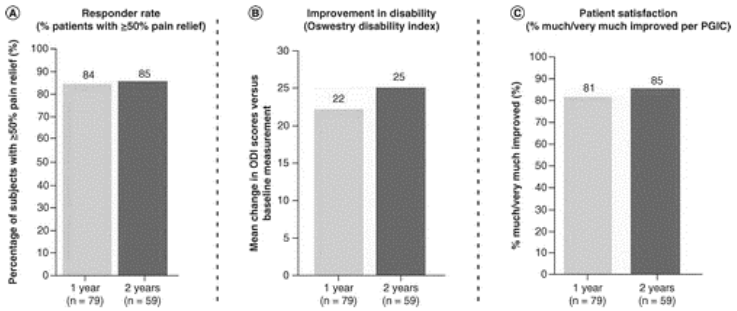

Figure 6. Long-term follow-up (1 and 2 years).

(A) Responder rate. **(B)** Mean change in ODI scores versus baseline measurement. **(C)** Percentage of subjects reporting much or very much improved per PGIC.

ODI: Oswestry Disability Index; PGIC: Patient Global Impression of Change.

Aggregate Analytics excluded these and other randomized trials to the detriment of an informed review by the State. Results from COMBO inform clinical decision-making and inform conditions for coverage by the Washington State Health Care Authority. We invite you to review publications in their entirety and collaborate with clinical experts in their use of FDA-approved devices for chronic pain.

3. Long-Term Safety & Durability of Treatment Response

Spinal cord stimulation for chronic pain has been available for more than 40 years. As with all medical technologies, diagnostics and therapeutics, each evolve based upon advancements and further understanding of disease. As a global leader enabling patient outcomes across a broad spectrum of care, investments of resources in collaboration with the clinical community will continue. As a hub for innovation[16], we encourage Washington State participation in those efforts to ensure local policy and population health objectives are achieved.

AAI relies heavily upon the discredited and Dutch-based Hara[17] article as the foundation of their analysis. Credible analyses of product safety may be found throughout peer reviewed and published literature. Published in February 2023, Rauck et al[18] evaluated the long-term safety of SCS. Registry data from 79 implanting centers[*] reported data from 1,881 enrolled patients. 1,776 patients underwent trial stimulation, from which 1,289 received permanent SCS implant. The annualized rate of device explant was 3.5% (all causes), and 1.1% due to inadequate pain relief. Total incidence of device explantation after 3 years was 7.6% (n = 98). Of these, 32 subjects (2.5%) indicated inadequate pain relief as cause for removal. Implant site infection (11 events) was the most common device-related serious adverse event (<1%). This prospective, global, real-world study demonstrates a high-level of safety for SCS with low rate of explant/serious adverse events. Moreover, subjects reported their overall improvement or impression of change at follow-up compared with baseline, and 88.2% reported overall improvement at 3-year follow-up.

These are but a few trials selectively excluded by AAI. Consideration of the body of evidence leads only to the conclusion SCS has been proven safe, enables personalized health care and delivers repeatable results superior to alternatives for chronic pain patients.

B. SPINAL CORD STIMULATION ELIMINATES OR REDUCES OPIOID USE AS DEMONSTRATED IN CLINICAL TRIALS AND REAL-WORLD EXPERIENCE

The Washington State Intractable Pain Act [WAC 246-919-850][19] attempts to clarify laws around pain management, particularly to the use of controlled substances and "encourage pain management". The State law provides, "[t]he medical management of pain should consider current clinical knowledge, scientific research, and the use of pharmacologic *and nonpharmacologic modalities according to the judgment of the physician*." [Emphasis Added].

[*] Two representative sites from Washington State included the Washington Center for Pain Management (Bellevue, WA) and Evergreen Health Neurosurgery (Kirkland, WA).

Within its own analysis, Aggregate Analytics[20] acknowledged their report was "…not a substitute for sound clinical judgment…" to which the State should trust experienced physicians and their patients with the care they deem medically necessary and supported by the body of evidence, professional societies and public health agencies across the globe.

In deference to community care standards, Washington State officials are encouraged to review published guidelines[21]. For example, the American Society of Regional Anesthesia and Pain Medicine (ASRA) issued the most current guidelines recommending SCS[22].

1. SCS Recommendations Directly Linked to Evidence of Opioid Reduction or Elimination

The 2019 U.S. Health & Human Services Inter-Agency Task Force Pain Management Best Practices[23] recommended use of spinal cord stimulation as an alternative to opioid use for chronic pain. Participating agencies such as CMS, Military Health, academia and non-industry participants issued their recommendation based upon high quality, peer reviewed and published evidence.

2. Real World Data Shows Long-Term Durability, Reduction or Elimination of Opioids Co-Medication with Gabapentinoids & Poly Therapy Significantly Reduced

Through a collaboration with clinical leaders from Harvard University and the University of Michigan, Dr. Jason Yong, Dr. Parag Patil and Dr. Christopher Gilligan evaluated the effects of spinal cord stimulation on longer-term opioid and non-opioid use among patients with ≥3 years of follow-up. Using the Merative™ MarketScan® Commercial Database[24]. Patients age ≥18 who initiated SCS between January 1, 2010 and March 31, 2021 with ≥1 year of baseline data and ≥3 years of follow-up data were included. Opioid discontinuation, dose reduction, proportion of days covered (PDC), concomitant co-medication with benzodiazepines and/or gabapentinoids, and polypharmacy were evaluated during baseline and follow-up periods. Adjusted logistic regression was used to evaluate the impact of baseline dosages on discontinuation and dose reduction.

During follow-up, 75.5% of 2,669 SCS patients either discontinued opioid use or reduced opioid daily dose from baseline. Logistic regression showed patients with higher baseline dosages were less likely to discontinue opioids completely (Odds ratio[OR] 95% Confidence Intervals[CI]:0.31[0.18,0.54]) but more likely to reduce their daily dose (OR[CI]: 7.14[4.00,12.73], $p<0.001$). Mean PDC with opioids decreased from 0.58 (210 of 365 days) at baseline to 0.51 at year 3 ($p<0.001$). With SCS, co-medication with benzodiazepines decreased from 47.3% at baseline to 30.3% at year 3, co-medication with gabapantenoids reduced from 58.6% to 42.2%, and polypharmacy dropped from 15.6% to 9.6% (all $p<0.001$).

Generalizable to individuals covered under the State's health plans, SCS directly aligns with opioid-alternatives, avoidance of drug-to-drug interactions and long-term dependency, mental and physical harm or death[25,26].

3. Number Needed to Treat (NNT)

McVicar eloquently explains the NNT construct: "The reciprocal of the attributable effect is the number needed to treat (NNT) which amounts to the number of patients that would need to be treated before one patient could be deemed to have benefited because of the specific effects of the intervention. High values of NNT (such as 10 or greater) indicate a poor treatment, for too many patients would need to be treated in order to achieve one legitimate success. Values of NNT of 2 or 3 indicate that a treatment is effective".

Prevailing non-opioid pharmaceutical options have high numbers needed to treat with gabapantenoids above 7, and selective nor epinephrine inhibitors at above 6 and topical medications above 10[27]. Hence, the data compiled from 96 randomized controlled trials and more than 26,000 subjects concluded that in reality, "usual care" does not work in most patients afflicted with chronic high impact pain[28]. By contrast, even with older technologies using paresthesia-based stimulation for complex regional pain syndrome and failed back surgery syndromes, the Ontario Health Technology assessment reports NNT of 3 for spinal cord stimulation for these patients[29]. In 2022, Matis observed significant advances in technology that targets new mechanisms of action (surround inhibition), even decreases pain that is nociceptive and mixed (nociceptive plus neuropathic)[30]

C. SPINAL CORD STIMULATION HAS BEEN PROVEN COST EFFECTIVE FOR PATIENTS SUFFERING FROM INTRACTABLE CHRONIC PAIN

Simpson's 2009[31] analysis incorporated a comprehensive literature review of cost and clinical effectiveness. Economic analyses modeled the cost-effectiveness and cost–utility of SCS in patients with neuropathic or ischemic pain. Eleven randomized controlled trials were included, evaluating clinical outcomes associated with FBSS and CRPS. Further studies considered QALY's gained for comparisons to CABG and percutaneous coronary interventions (PCI). The evidence suggested SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. SCS dominated (it cost less and accrued more survival benefits) over CABG.

Kumar et al (2013)[32] concluded SCS was cost-effective when compared with conservative medical management (CMM). Markov models were developed to evaluate the cost-effectiveness of SCS vs CMM alone from the perspective of a Canadian provincial Ministry of Health. Each model followed costs and outcomes in 6-month cycles. Health effects were expressed as quality-adjusted life years (QALYs). Costs were gathered from public sources and expressed in 2012 Canadian dollars (CAN$). Costs and effects were calculated over a 20-year time horizon and discounted at 3.5% annually, as suggested by the National Institute of Clinical Excellence. Cost-effectiveness was identified by deterministic and probabilistic sensitivity analysis (50,000 Monte-Carlo iterations). Outcome measures were: cost, QALY, incremental net monetary benefit (INMB), incremental cost-effectiveness ratio (ICER), expected value of perfect information (EVPI) and strategy selection frequency.

The ICER for SCS was: $9,293 (FBSS), $11,216 (CRPS), $9,319 (PAD), and $9,984 (RAP) per QALY gained, respectively. SCS provided the optimal economic path according to researchers. The probability of SCS being cost-effective compared with CMM was 75–95% depending on pathology. Sensitivity analyses demonstrated results were robust to plausible variations in model costs and effectiveness inputs. Per-patient EVPI was low, indicating that gathering additional information for model parameters would not significantly impact results.

Duke University professor Dr. Harrison Farber (2017)[33] also evaluated cost-effectiveness of SCS compared with conservative medical management (CMM) for failed back surgery patients. Of the 122,827 within their cohort, 5,328 underwent SCS implantation. Total annual costs decreased over time following implantation of the SCS system, with follow-up analysis at 1, 3, 6, and 9 years. While there was an initial cost increase due to the SCS procedure, there was a significant and sustained 68% decrease in cost in the year following SCS placement [CR: 0.32; 95% CI: 0.24, 0.42, $P < 0.001$] compared to CMM. There was also an aggregate time trend that for each additional year after SCS, cost decreased on average 40% annually [CR: 0.60; 95% CI: 0.55, 0.65, $P < 0.001$], with follow-up up to 1, 3, 6 and 9 years post-procedure.

D. EQUITABLE ACCESS TO SPINAL CORD STIMULATION ALIGNS TO WASHINGTON POLICY OBJECTIVES

Along with U.S. Medicare[34] and Medicare+Advantage programs, NICE (UK)[35] and HAS (France)[36] both enable access to SCS finding evidence sufficient to enable access to address neuropathic chronic pain. Regional health plans including United Healthcare[37], Aetna[38], Humana[39], Premera[40], Regence[41] and others all cover SCS for FBSS and CRPS I and II. Each align to recommendations from authoritative sources following extensive review of published evidence. Washington appears to be an outlier for its non-coverage position.

In summary, robust clinical evidence supports SCS use for state employee benefit programs, Apple Care, workers compensation and other programs included within the State's coverage position. We strongly encourage reconsideration based upon the most current evidence, technology advancements and alignment with community standards of care.

Sincerely,

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[39] Humana CPB HUM-0306-026 (rev. 24 August 2023) accessible at: https://apps.humana.com/tad/tad_new/home.aspx?type=provider

[40] Premera BCBS CPB 7.01.25 (rev. 12 June 2023) at: premera.com/medicalpolicies/7.01.546.pdf

[41] Regence BCBS CPB Surgery #45 (rev. June, 2023) at: https://blue.regence.com/trgmedpol/surgery/sur45.pdf

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Comments on Draft HTA: Spinal Cord Stimulation
Date: Monday, October 2, 2023 1:08:44 PM
Attachments: 2023-10-02 AdvaMed WA HTA SCS Comments FINAL.pdf

External Email

Good afternoon,

The Advanced Medical Technology Associations (AdvaMed) appreciates the opportunity to provide comments on the draft evidence report for spinal cord stimulation under consideration at the Washington State Health Care Authority. If you have any questions regarding these comments, please feel free to contact me [redacted]) at your convenience.

Yours,
Kirsten

Kirsten Tullia
Senior Vice President, Payment and Healthcare Delivery Policy
(she/her)
[redacted]

AdvaMed
Advanced Medical Technology Association

October 2, 2023

Washington State Health Care Authority
Health Technology Assessment Program
Via Electronic Mail at shtap@hca.wa.gov

RE: State of WA Health Care Authority – 2023 Draft Report: Spinal Cord Stimulation

Dear Director Birch,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the draft HTA report on spinal cord stimulation (SCS). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

We appreciate the challenging work conducted by the Washington State Health Care Authority (HCA), and its impact for the citizens of Washington. The HCA has tackled many complicated questions over the years, subjects ranging from Breast MRIs, Glucose Monitoring, to Bariatric Surgery. These evaluations appeared to have used relevant clinical data to help inform policy making for the State of Washington. Additionally, with these examples and many of the other assessments, these evaluated topics have all undergone significant changes in the available technologies, the evidence and the available outcomes.

The most recent HCA re-review of interest is on SCS, which was originally evaluated in 2010, and again in 2014, 2016, and 2018. We appreciate the HCA's commitment to conducting a further review because widespread coverage is available for SCS across the US and, over the past several years, the body of evidence has only continued to grow.

The technology of using electrical stimulation of the spinal column to treat chronic intractable pain provides a treatment option to allow patients suffering from chronic pain to get actual relief. SCS demonstrates an improvement in quality of life for patients who suffer from chronic pain as a treatment option when multiple first-line therapies have failed. It also provides a treatment option to address the unprecedented opioid crisis in our country – approximately 9.5 million

Americans are misusing opioids, with 65 percent doing so to relieve physical pain.[1] This is why most national and regional payers recommend SCS when patients have tried and failed multiple conservative medical management treatment options.[2].

While we recognize the significant efforts that went into the latest report and review, our members have serious concerns with the final evidence used to derive the recommendations included for the Health Technology Clinical Committee (HTCC) review. Industry, as developers of devices and therapies including SCS, is uniquely positioned to play a constructive role in identifying technologies that bring the greatest benefit to patients while ensuring value to the health care system. It is in this interest that AdvaMed, and our members companies, are commenting on the SCS Draft HTA. We encourage Washington State HCA to seriously consider these comments and those of the AdvaMed member companies submitted separately. We appreciate the opportunity to submit these comments.

Comments on Draft HTA

There are several areas of concern related to the draft HTA on SCS. Those concerns include:

- **Evaluate the full body of evidence as part of the HTA**. It appears that several randomized studies that compare different types or modalities of SCS have been excluded from the draft HTA. We encourage the HTCC to ensure that the HTA includes a full evaluation of the totality of the evidence to allow for a thorough understanding of how SCS is used in current clinical practice. There are numerous well-designed randomized studies that were excluded from the draft HTA and we urge the HTCC to include the full list of relevant RCTs for consideration. Details of those studies have been provided by our member companies in separately submitted comment letters.
- **Recognize the broad coverage and acceptance of SCS as a current standard of care.** SCS has been universally accepted and adopted into the chronic pain continuum of care, both globally and nationally, and is covered by the Centers for Medicare and Medicaid Services, state workers compensation boards, and almost all commercial US health plans – the Washington State HCA stands alone in its sweeping non-coverage decision. The draft HTA currently fails to acknowledge multiple HTAs and national payer policies on SCS, thereby overlooking the persistent gap in coverage for Washington State's citizens suffering from chronic pain. In addition, the draft HTA does not acknowledge the multiple professional society guidelines supportive of the use of SCS for specific patients, including the American Society of Interventional Pain Physicians[3], American

[1] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56).
[2] Virtually all coverage policies include specific criteria for coverage including a patient must pass a trial/evaluation period demonstrating pain improvement of 50% or more prior to qualifying for a permanent implant.
[3] Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. 2013;16(2 Suppl):S49-283

Society of Anesthesiologists[4], American Pain Society[5], and the Neuromodulation Therapy Access Coalition[6].

Summary

Given the limitations of the current draft report, AdvaMed urges the Authority to commit to its own processes, which state that a coverage determination is made not only based on the evidence report, but also the comments such as ours and other relevant stakeholders. We strongly urge the Authority to classify SCS a technology which has a "unique impact on a specific population based on factors such as sex, age, ethnicity, race, or disability" as listed in the clinical committee meeting and decision process. Patients living with chronic, intractable pain who have no other treatment option but to remain on high-dose oral opioids can benefit through access to SCS – which is afforded to other populations within the state today. SCS continues to be a safe and effective treatment option for patients who suffer from chronic pain. The science has been proven through multiple randomized clinical trials that have studied this treatment compared to conventional medical management. With recent advancements in technology to address clinical needs with multiple platforms, contemporary randomized trials have continued to yield positive results in providing more personalized treatments for complex pain patients where limited alternatives exist. We implore the Washington State HCA to re-evaluate the newer evidence that was not addressed in their review. It is unfortunate that Washington State HCA remains the only outlier in the US that fails to cover SCS for the most disadvantaged and vulnerable populations which include their Medicaid and workers compensation programs. This presents a significant health disparity as there is a proven benefit that SCS provides when multiple conservative therapies have failed.

Therefore, AdvaMed requests the draft report be amended to: (1) evaluate the full body of evidence as part of the HTA; (2) recognize the broad coverage and acceptance of SCS as a current standard of care. AdvaMed further requests the HTCC exercise their respective expert clinical judgment and align Washington State with the rest of the country by either: (1) covering SCS technology; or (2) covering the technology under specific circumstances – such as limited to specific indications and/or with prior authorization review.

We appreciate this opportunity to submit comments as part of this process. If you have any questions, please contact Kirsten Tullia [redacted]).

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[4] American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. 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(4):810-833.

[5] Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). 2009;34(10):1066-1077

[6] North R, Shipley J. Practice Parameters for the Use of Spinal Cord Stimulation in the Treatment of Chronic Neuropathic Pain. Pain Med. 2007;8(s4):S200-S275

From: [redacted]
To: HCA ST Health Tech Assessment Prog; Amol Soin
Subject: WA Health Care Authority – 2023 HTA Topic Assessment: Spinal Cord Stimulation
Date: Saturday, September 30, 2023 12:23:40 PM
Attachments: asipp letter to WA on scs.pdf

External Email

ATTACHED is the comments from ASIPP regarding the Spinal Cord Stimulation Topic which comments are due October 2nd

Thank you

--
Amol Soin, MD
Anesthesiology/Pain Management

American Society *of* Interventional Pain Physicians®
"The Voice of Interventional Pain Management"
[redacted]

RE: WA Health Care Authority – 2023 HTA Topic Assessment: Spinal Cord Stimulation

Submitted online to shtap@hca.wa.gov

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ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 48 state societies (including Washington via our Washington Society of Interventional Pain Physicians) of Interventional Pain Physicians, including Puerto Rico and the affiliated Texas Pain Society.

Interventional pain management is defined as , "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment" (http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf).

Interventional pain management techniques are defined as, "minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain". (https://permanent.fdlp.gov/lps21261/dec2001PainManagement.pdf

We are reaching out to you as a citizen and a leader of the Washington Society of Interventional Pain Physicians for the state of WA Health Care Authority – 2023 HTA Topic Assessment: Spinal Cord Stimulation (scs).

We are grateful that you all are taking the time to re-review spinal cord stimulation based upon new evidence. As you correctly mentioned there are now 16 different FDA approved products offering stimulation and several studies which support their use.

I am writing to express my strong support for the consideration and implementation of spinal cord stimulation (SCS) as a viable and cost-effective treatment option for patients suffering from chronic pain within the state of Washington. The evidence behind the efficacy and cost savings associated with SCS is compelling and warrants careful attention.

Over the past few decades, numerous clinical studies and medical research have consistently demonstrated the positive impact of SCS on patients with chronic pain conditions. Spinal cord stimulation involves the implantation of a device that delivers electrical impulses to the spinal cord, effectively modulating pain signals and providing significant relief to patients. Below are key findings from relevant studies:

Effectiveness of SCS: The landmark study by Kumar et al. (2015) [1] showed that SCS resulted in a 50% or greater reduction in pain in over 70% of patients with chronic back and leg pain. These findings were corroborated by a meta-analysis conducted by Taylor et al. (2018) [2], which demonstrated consistent and significant pain relief across multiple clinical trials.

Improved Quality of Life: Patients undergoing SCS treatment have reported significant improvements in their quality of life, mobility, and overall well-being. A study by North et al. (2017) [3] found that SCS not only reduced pain but also improved sleep, mood, and physical functioning.

Cost Savings: Implementing SCS as an early intervention strategy has been shown to lead to substantial cost savings for healthcare systems. A study published in the Journal of Pain Research by Manca et al. (2018) [4] highlighted the cost-effectiveness of SCS compared to conventional pain management methods.

Reduction in Opioid Use: SCS has the potential to reduce the reliance on opioid medications, which can lead to addiction and other adverse effects. A study by Hagiwara et al. (2019) [5] demonstrated a significant reduction in opioid use among SCS patients.

Considering the overwhelming body of evidence supporting the efficacy and cost savings associated with spinal cord stimulation, I urge the Washington State Department of Health to explore policies and initiatives that promote the availability and accessibility of this life-changing treatment option for patients suffering from chronic pain.

Additionally, in the PICTOS Draft – one concern we have is that you are excluding studies which compare different waveforms with each other. Given the rise in new technologies and waveforms, there are several head-to-head RCTs which will provide actionable intelligence and excellent data while offering head to head comparisons.

Finally, looking at the PICTOS criteria, one significantly flawed trial design (Hara et al) may meet criteria for inclusion, and we suggest that you review the study design closely. There are several published letters to the editor that provide additional context which I am attaching here on the flawed design. On a similar note, there is another flawed reference on costs from Dhruva et al that we feel should also be disqualified as there are significant flaws in the study design and quite frankly- those authors had financial interests that benefit greatly from the flawed conclusions in the paper. It is quite concerning to use those articles as a basis to deny care.

ASIPP is grateful for the opportunity to provide comments on this important issue, and we are glad to see Washington doing this topic assessment.

By embracing SCS, Washington state can not only improve the lives of individuals living with chronic pain but also contribute to reducing the burden on healthcare resources and curbing the opioid epidemic.

Thank you for your time and attention to this matter. I look forward to seeing Washington take a proactive stance in enhancing the well-being of its residents

References:

1) Kumar, K., Taylor, R. S., Jacques, L., & Eldabe, S. (2015). 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, 77(5), 815-827.

2) Taylor, R. S., Desai, M. J., Rigoard, P., & Taylor, R. J. (2018). Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. Pain Practice, 18(5), 605-618.

3) North, R. B., Kidd, D. H., Farrokhi, F., & Piantadosi, S. A. (2017). Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery, 81(3), 397-405.

4) Manca, A., Kumar, K., Taylor, R. S., Jacques, L., & Eldabe, S. (2018). Spinal cord stimulation for chronic pain. Journal of Pain Research, 11, 1759-1765.

5) Hagiwara, S., Iwasaka, H., Takeshima, N., & Noguchi, T. (2019). Spinal cord stimulation reduces the risk of opioid use after lumbar spine surgery: a systematic review and meta-analysis of randomized controlled trials. Pain Physician, 22(4), 309-318.

Sincerely,

Amol Soin, MD
Immediate Past President, ASIPP
President, SIPMS
CEO, Ohio Society of Interventional Pain Physicians
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Response to SCS rereview
Date: Monday, October 2, 2023 12:41:50 PM
Attachments: 231002 Letter to Washington State Health Care Authority.pdf

External Email

Hello,

Please find attached a response to the WSHCA's rereview of spinal care stimulation, sent on behalf of 12 medical societies. Can you please confirm receipt?

If you have any questions, please do not hesitate to reach out.

Sincerely,
Keri

KERI KRAMER | **CEO**
NORTH AMERICAN NEUROMODULATION SOCIETY

[redacted]

[redacted]

October 2, 2023

Sue Birch, MBA, BSN, RN
Director
Washington State Health Care Authority
Cherry Street Plaza
626 8th Avenue SE
Olympia, Washington 98501
Via e-mail: shtap@hca.wa.gov

RE: WASHINGTON STATE HEALTH CARE AUTHORITY SEPTEMBER 1, 2023 DRAFT EVIDENCE REPORT SPINAL CORD STIMULATION (SCS) REREVIEW

Dear Ms. Birch:

On behalf of the more than 95,000 members our undersigned societies represent, we greatly appreciate the opportunity to submit these written comments addressing the Washington State Health Care Authority (WSHCA) September 1, 2023 Draft Evidence Report, Spinal Cord Simulation (SCS) Rereview (hereafter, "Draft Rereview") prepared by its contractor Aggregate Analytics, Inc (hereafter, "AAI"). The original WSHCA SCS Review was released July 23, 2010 (hereafter, "Original Report"); two Signal Assessment updates were released on December 29, 2014 (hereafter, "First Signal Assessment") and on August 29, 2016 (hereafter, "Second Signal Assessment").

Our membership consists of anesthesiologists, neurologists, neurosurgeons, orthopedic surgeons, physiatrists, psychologists, engineers, other scientists, and health care professionals. We are all dedicated to improving the care patients receive when dealing with chronic neurologic disorders, including, as in the case of SCS, severe debilitating pain.

We believe that our goals are substantially aligned with those of WSHCA and we wish to start off by recognizing two of your efforts that exemplify this alignment. We applaud the active role that WSHCA took in the recent International Overdose Awareness Day on August 31, 2023.[i]

This effort builds on the longstanding effort of the WSHCA Friends for Life program that aims to prevent opioid and, more specifically, fentanyl overdoses.[ii] Likewise, we commend WSHCA for its efforts in addressing suicide prevention by focusing its efforts on September as "Suicide Prevention Month."[iii] The clinical setting of severe, chronic debilitating pain -- the clinical setting in which SCS should be considered as an evidence-based and guideline-directed treatment alternative -- is exactly the type of situation in which opioid therapy may be initiated or continued, thereby starting the spiral toward opioid

misuse/abuse. Finally, a clinical setting of chronic unremitting pain is associated with increased rates of suicide that patients may consider when they see no other option to relieve their pain.

We want to acknowledge the important and serious role that WSHCA has in this process; it has the authority to establish and modify coverage policies for two and a half million Washingtonians through WSHCA plans (Washington State Employees Health Plan and Washington Medicaid) and through the Washington State Workers' Compensation Insurance program. In this particular case, the issue in front of the Committee is whether the Committee accepts the Draft Rereview. And what hangs in the balance is whether members in these three programs will have access to SCS as a covered benefit. AAI has provided the Draft Rereview as a key input to your decision-making process:

> "The aim of this report is to systematically review, critically appraise and synthesize research evidence evaluating the effectiveness and safety of SCS for treatment of pain related to failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), or peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia) in adults who are SCS-naïve. The differential effectiveness and safety of these therapies for subpopulations will be evaluated, as will cost-effectiveness." (p. 2)

We appreciate that members of the AAI team have deep methodological expertise in technology assessment and epidemiology. We also appreciate greatly the wisdom of a sentence they wrote on page i of the Draft Report:

> "Information in this report is not a substitute for sound clinical judgement."

At several steps in the development of this Draft Rereview, our societies and our members have attempted to provide, in the spirit of "sound clinical judgement," clinical input to the process. We are saddened to say that this input has been essentially ignored in its entirety. We are concerned that our earnest efforts at providing "sound clinical judgement" may have been considered by AAI as attempts to introduce bias into their technology assessment process. Unfortunately, with each step over time, "sound clinical judgement" was repeatedly rejected, and we contend that another type of bias was introduced into the process. The Draft Rereview no longer addresses the clinical reality of managing chronic, debilitating back pain for patients in the US and in Washington State, in particular. It is our opinion that the AAI Draft Rereview is significantly flawed, and it should not be accepted nor acted upon by WSHCA. We believe that doing so would sully the reputation of WSHCA as a robust, disciplined, and clear-thinking policy development organization. Regrettably, we must recommend that you reject the Draft Rereview

at your upcoming meeting and immediately initiate a process of creating a new report that welcomes "sound clinical judgement" and addresses the issues outlined in this letter. We welcome the opportunity to engage with you in such a process.

The peer-reviewed, published clinical literature has shown SCS be a cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates.

To facilitate navigation, this letter is divided into six Sections:

I. The magnitude of chronic pain as a clinical/economic issue
II. Differential performance of SCS in health benefits and Workers' Compensation
III. SCS & the Standard of Care (SoC) for pain management
IV. Current coverage status for SCS
V. Clinical critique of the AAI Draft Rereview
VI. Our Conclusions & Recommendations

I. The Magnitude of Chronic Pain as a Clinical/Economic Issue

Chronic pain is an issue of massive size in the US. 50 million individuals are afflicted by daily pain, including 17.1 million suffering from high-impact chronic pain (i.e., chronic pain that results in substantial restriction to daily activities).[iv] According to the US Centers for Disease Control and Prevention (CDC), chronic (i.e., pain lasting three or more months), debilitating pain affects daily work and life activities for many adults in the US; it has been linked with depression, Alzheimer's disease and related dementias, higher suicide risk and substance use and misuse.[v,vi] Comorbidities resulting from pain can include obesity, heart disease, increased risk of diabetes, as well as a significant mental health burden on the patient and their family members.

The cumulative economic burden for chronic pain is projected to be $500 billion this year.[vii] In the US, the loss of productivity due to chronic pain was estimated to be $61.2 billion per year in 2003 and has continued to increase year-over-year.[viii] Studies have shown that increased unemployment and absenteeism are associated with poor quality of life, depression and generally poor health outcomes.[ix] Lardon, et al. found that approximately two-thirds of the total economic burden of chronic pain are the indirect costs – related to loss of productivity or working days lost.[x]

II. The Differential Performance of SCS in Health Benefits and Workers' Compensation

The Committee decision has a direct impact on two types of programs through which benefits for SCS treatment of chronic, severe pain are administered. One is through health benefits and the other is through Workers' Compensation Insurance. It is commonly appreciated in the clinical pain management community that treatment of patients in the Workers' Compensation environment is often less effective than the same treatment applied to a population of identical patients treated on a health care benefit. Importantly, the authors of Hollingworth, *et al.*, a key cost-effectiveness publication in the Draft Rereview, state this differential effectiveness matter-of-factly in their discussion section: "Furthermore, workers' compensation claimants **have worse outcomes** than other patients after a variety of pain therapies."[xi] They, next provide two references in support of this statement.[xii, xiii] The Draft Rereview specifically confirms this assertion on p. 121: The authors of Hollingworth "note, in general, Worker's Compensation claimants **may have worse outcomes** following treatments for pain compared with other populations." (emphasis added) The authors of Hollingworth actually state that Workers' Compensation **have worse outcomes** compared with other populations, and AAI has undercommunicated and misrepresented the Hollingworth, *et al.* authors' statement. We believe that the findings of Hollingworth, *et al.* should not be applied to a health benefit population and that the authors themselves state that to be the case. The Draft Rereview indicates that:

> "To evaluate differential efficacy and safety (heterogeneity of effect, interaction), we focused on RCTs as they have the least potential for bias and confounding thus allowing for causal inference. Further, only RCTs that formally tested for interaction between subgroups were considered for Key Question 3. No trials meeting our inclusion criteria that evaluated heterogeneity of treatment effect were identified." (p. 69)

We believe that the requirement of an RCT to show differential effectiveness in two sub-populations is impractical, arbitrary, and capricious. One structured literature review and meta-analysis found 175 studies that stated that the presence of compensation (workers' compensation with or without litigation) was associated with a worse outcome in patients while 35 found no difference or did not describe a difference; then, meta-analysis of 129 studies with available data (n = 20 498 patients) revealed the summary odds ratio for an unsatisfactory outcome in compensated patients to be 3.79 (95% confidence interval, 3.28-4.37 by random-effects model).[xiv] This plus the misquoted statements of Hollingworth, *et al.* should be sufficiently compelling data for establishing the two sub-populations.[xv]

In particular, we believe that utilizing the Hollingworth, *et al.* data to describe the effectiveness of SCS in a health benefit population, as the analysis currently stands, introduces an important bias

into the Draft Rereview that should not be permitted. This approach could be expected to result in an understatement of the effectiveness of SCS in the health benefit population and might also result in inadvertently not extending coverage when a decision to extend coverage in health benefits plans is more appropriate.

Request: We, respectfully, request that two sub-populations of patients are developed (as is appropriate per Question 3) to create separate sub-analyses for Workers' Compensation and health benefit coverage populations based on the differential effectiveness in the two populations. This division should be performed in a manner that the findings of Hollingworth, *et al.* are not applied to a health benefit coverage population. This request is consistent with peer-reviewed, published meta-analysis data, the statement of differential effectiveness between the two populations made by the authors of Hollingworth, *et al.*, and the broader clinical literature. The AAI requirement for a specific RCT to support such a request is arbitrary and capricious.

III. SCS & the Standard of Care (SoC) for Pain Management

There is a bias in the layout of the Draft Rereview in that certain Sections have no explanatory text. Section 2.7 is problematic in this regard. It is markedly different from Sections 3, 4, and 5.

The Standard of Care (SoC) for Pain Management is defined by published clinical guidelines. Section 2.7 of the Draft Rereview "Published Clinical Guidelines" contains Table 3 "Summary of Clinical Guidelines." The only accompanying text is a list of these Guidelines. There is no accompanying explanation of the Guidelines. Table 3 presents a summary of ten Published Clinical Guidelines from several different organizations and countries. The consensus of all these Guidelines is that there is a role for SCS as a SoC technology after a prolonged effort to control pain and failure of several less invasive measures. SCS has been shown to be a cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates. Simply put, they all agree that SCS is a SoC clinical intervention that "should be performed" or "can be performed" in such a clinical setting.

We believe that the synthesis and communication in the Draft Rereview is not sufficient for the Committee to be aware that SCS is a universally accepted SoC therapy globally and that the decision not to extend coverage to SCS is an action in contradiction to all ten of the Published Clinical Guidelines in Section 2.7. We believe that, as part of the "Background" (overarching title of Section 2 of the Draft Rereview) and in the spirit of "sound clinical judgement," the Draft Rereview should summarize Table 3 with a statement to the effect that "all ten Published Clinical Guidelines support the role of SCS as a SoC procedure." It is unstated anywhere in the Draft Rereview that a decision to accept the Draft Rereview and not to extend coverage to SCS is an

action in conflict with the SoC described in all ten of these Guidelines, and we believe that omission, by itself, is a significant bias in the Draft Rereview as it currently stands.

As far as the contents of these specific Published Clinical Guidelines mentioned in Table 3, the 2023 American Society of Regional Anesthesia and Pain Medicine (ASRA) recommends SCS implantation following protracted efforts with less aggressive measures and after a successful trial of a short-term SCS.[xvi] These Guidelines point out that psychosocial factors, patient education, and personalized objectives in treatment must be addressed. Also, mentioned in Table 3, the American Society of Interventional Pain Physicians (ASIPP) published its guidelines in 2013 recommending the use of SCS.[xvii] We request that a statement is added to the Draft Rereview stating that the consensus of the ten Guidelines in Table 3, including the two most recent US Guidelines for pain management, both identify SCS as a SoC procedure following a protracted effort to control pain with less aggressive measures. We want to be certain that AAI informs the Committee in a transparent manner that continuing not to extend coverage to SCS is a position in defiance of all ten Guidelines. Why are Guidelines included in the Draft Rereview if not to transparently inform the Committee of the context of the decision it is being asked to make?

Through a process modeled after the 2019 HHS Task Force best practice recommendations for SCS, Bates, *et al.* reviewed and synthesized all available practice guidelines and care algorithm encouraging timely referral to the pain specialist.[xviii] Their pathway placed SCS as a "fourth-line treatment," following optimized medical management by the pain specialist, with SCS considered just prior to the long-term use of opioids. This document outlines how failure of a more robust multi-disciplinary and multi-modal care pathway by a pain specialist is necessary today for a patient to be considered a candidate for SCS.

> **Request:** We request that text is added to Section 2.7 of the Draft Rereview synthesizing and communicating the information in Table 3 in a more transparent manner. We believe that the current lack of text synthesis in the Draft Rereview is a bias. Specifically, we wish that text is added explaining that the consensus of all ten Guidelines presented in Table 3 is clear and consistent that SCS is a SoC technology appropriate after prolonged and multi-faceted attempts to control pain through less aggressive measures have failed. We believe that this level of transparency is necessary for the Committee and other stakeholders (including our societies) to understand that should a decision to accept the Draft Rereview occur, and that coverage is not extended to SCS, the Committee is aware that it is rejecting the broad international consensus of the clinical community that SCS is the SoC.

IV. Current Coverage Status for SCS

Similarly, there is a bias in the layout of the Draft Rereview in that Section 2.9 underreports health plans coverage of SCS, and there is no explanatory text providing sufficient "Background."

"Which health plans are currently covering SCS?" We believe that the Draft Rereview presents this information in an imprecise and biased fashion. Both Section 2.9 and Table 6 are titled "Medicare and Representative Private Insurer Coverage Policies." Section 2.9 consists of only Table 6 with no explanatory text, and no explanatory context is provided. This is the only Section of the Draft Rereview with no accompanying text to explain the process or findings. Table 6 lists Medicare, Aetna, and CIGNA as health plans extending coverage to SCS. While that is technically accurate information, we believe that this level of explanation in Table 6 is another example of biased communication and a disservice to the Committee.

As we prepared to respond to the Draft Rereview, we informally surveyed our members and asked, "Which US payers are currently covering/not covering SCS?" The answer was that all payers in the US are currently extending coverage for SCS with the exception of WSHCA Health Plans. At one point, there were two that did not cover SCS, WSHCA and Oregon Medicaid, but over five years ago Oregon Medicaid extended coverage for SCS, leaving WSHCA as the lone holdout in the US for now over five years. Even in the State of Washington, WSHCA is an outlier. More Washingtonians have access to SCS as a covered benefit through traditional Medicare,[xix] Medicare Advantage health plans, Premera Blue Cross and Blue Shield,[xx] and Kaiser Permanente Washington[xxi] than those who don't have access through a WSHCA health plan. We contend that the identification of current payers is pertinent information for the Committee to consider, and AAI knows this because the Draft Rereview contains Section 2.9 and Table 6. By contracting AAI to create a Draft Rereview that includes a Section 2.9 "Medicare and Representative Private Insurance Coverage Policies," WSHCA acknowledges that this issue is germane to the decision before the Committee. We are concerned by the omission of these germane facts as a significant bias in the Draft Rereview.

With the exception of WSHCA Health Plans, all health benefit plans across the US (even in traditional Medicare) provide benefits to SCS through an intensive Prior Authorization (PA) process that assures patients who receive SCS have, essentially, no other alternative to pursue. These PA processes require that criteria similar to the following are met prior to the performance of any procedure (the following is adapted from Premera criteria that can be accessed through the link embedded in Reference xx):

- The treatment is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have failed, or are judged to be unsuitable or contraindicated.

  AND

- The individual has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves (such as failed lumbar back surgery syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pan, peripheral neuropathy, or panful diabetic neuropathy).

  AND

- Member has obtained clearance by a licensed psychologist, psychiatrist, or other licensed mental health professional.

  AND

- No untreated drug habituation exists.

- Placement of a permanent spinal cord stimulator may be considered medically necessary when the above medical necessity criteria for a trial spinal cord stimulator are met, and there is demonstration of at least 50% reduction in pain with at least 3-day trial of temporary spinal cord stimulation.

It is our understanding that WSHCA health plans currently have PA processes in place for other services. So, implementing PAs for SCS as a process would not be an undue hardship for the health plans. The intention of all these PA processes is that SCS is only used in a small number of patients who are at the end of the road and have no other therapy available to them. It is for those patients at the "tip of the iceberg." The Draft Rereview in its current form omits any discussion of SCS procedures requiring PA uniformly across the US for benefits for SCS to be paid.

Request: We respectfully request that explanatory text is added to Section 2.9 of the Draft Rereview to make it transparent to the Committee that **all health benefit plans in the US with the exception of the Washington State Employees health plan and Washington Medicaid extend coverage to SCS and all other health plans are managing SCS through prior authorization.** While the Committee clearly has the authority to make the decision to be the last health benefit decision-maker in the US to fail to extend coverage to SCS, we believe that having a Draft Rereview that fails to inform the Committee of this aspect of their decision introduces a significant bias into the process. It is important for the Committee, when adopting any report, that it receives comprehensive information on all aspects of the issue. The undercommunication in Section 2.7 and 2.9 of the Draft Rereview are important biases in the report and a disservice to the Committee.

Let us now proceed to the more nuanced assessment of the clinical issues with the Draft Rereview.

V. Clinical Critique of the AAI Draft Rereview

From the beginning of this process, our societies and our members have attempted to provide "sound clinical judgement" to the processes of developing questions, of selecting studies for inclusion and exclusion, and synthesizing the selected studies into conclusions. While our comments were offered in the spirit of contributing "sound clinical judgement" that the Draft Rereview itself points out is irreplaceable, it is disheartening, at this late point in the process, that our input has been for all practical purposes rejected. Our "sound clinical judgement" seems to be viewed as a confounding bias in the report development, and the Draft Rereview has suffered as a result.

At the current point in the process, it is our belief that the Draft Rereview does not reflect the clinical literature and is simply indefensible. We are deeply saddened that we have to reach this conclusion because throughout the process we and our members have provided input in good faith to create a sound output, only to have such input repeatedly ignored. The misunderstanding of the clinical evidence is so pervasive that we fail to see how the Committee can accept this Draft Rereview. From our perspective, the only step that would further exacerbate the situation would be for the Committee to accept and act on this deeply flawed Draft Rereview. Below is a small sample of the misinterpretation of the clinical literature that we have attempted to correct.

A. Evidence of Effectiveness for SCS

At the time the Draft Rereview was initiated, our understanding was that WSHCA was to look at the new data regarding SCS therapy.

The Original Report made the following very positive statement about SCS, "Current best evidence is available primarily from four trials on 375 patients, which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions." These trials included North (Level 2), Kumar (Level 1), Kemler (Level 1), and Turner (Level 2). This is, indeed, a very positive statement regarding the clinical evidence in support of SCS. Our interpretation is that this sentence indicates that SCS, as a technology, had more and higher quality data than other technologies that went on to be extended coverage by the WSHCA.

One of those studies, North, *et al*. followed patients for an average of three-years.[xxii] Prior to clinically indicated repeat spine surgery, subjects were randomized to repeat surgery or SCS. Evaluable subjects (n=45) in the SCS cohort were less likely to cross-over to repeat surgery (p =0.02). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS ($p < 0.025$). The investigators concluded that SCS was more effective than repeat surgery as a treatment for persistent radicular pain after unsuccessful lumbosacral spine surgery. This approach obviated the need for reoperation in the great majority of patients.

Another study, Kumar, *et al*. compared SCS to CMM in FBSS patients.[xxiii] The primary outcome was the proportion of patients achieving ≥50% pain relief in their legs. Secondary outcomes were improvements in back and leg pain, health-related quality of life, functional capacity, use of pain medication/non-drug pain treatment, level of patient satisfaction, and incidence of complications/adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6-months, 24 SCS (48%) and 4 CMM patients (9%) ($p < 0.001$) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved relief of leg and back pain, quality of life, and functional capacity, as well as greater treatment satisfaction ($p \leq 0.05$ for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications. The authors concluded that in selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.

Since that time, as mentioned above, ten Guidelines have been created reaffirming that SCS is the SoC and all payers in the US, with the exception of WSHCA Health Plans, have extended coverage to SCS. WSHCA seems to be a voice in the wilderness asking the question “Is SCS any better than CMM?” As a result, numerous studies comparing one SCS stimulation algorithm with another never made it into the Draft Rereview. The SoC is rapidly evolving toward these novel stimulation algorithms, some of which have response rates well above 80%, as reported by Perez (2021),[xxiv] Kapural (2022),[xxv] Mekhail (2023),[xxvi] and Fishman (2021).[xxvii] The new data showing greater than 80% response rates were systematically excluded while the thirteen-year-old Hollingworth study showing a 5% response rate remains central to the Draft Rereview analysis. We believe that it remains important to include these more recent studies as they all describe the performance of novel SCS stimulation algorithms as superior to traditional SCS.

Our “sound clinical judgement” has been that it is important for the Draft Rereview to include these publications and to document the degree to which novel stimulation algorithms (i.e., HF-

SCS, Burst-SCS, and others) are superior to traditional SCS. From our direct communication with WSHCA and with our members, we understand that the following nine publications were provided to AAI in the spirit of providing some "sound clinical judgement" and were rejected. Please add the following publications to the Draft Rereview:

- There is no reference in the Draft Rereview to Deer, *et al.* from 2017 which evaluated 100 subjects randomized to receive tonic (traditional) SCS or burst stimulation SCS.[xxviii] Results from the SUNBURST study demonstrated that burst SCS is safe and effective. At one year, significantly more patients preferred burst stimulation vs. tonic SCS (68.2% vs 23.9%, 8% no preference). Multimodal stimulation was found beneficial for these patients, enabling a treatment unique to a personalized patient need.

- In 2020, Hamm-Faber, *et al.* published pilot trial outcomes (n=9) evaluating high dose SCS in FBSS patients.[xxix] The Dutch Neuromodulation Society guidelines were used to screen subjects for SCS. Patients were screened through a trial period, common before permanent implantation of the generator. VAS leg pain at baseline was 71.2 ± 33.8 and reduced to 25.7 ± 24.0 at 6 months and 23.4 ± 32.0 at 12 months. VAS back pain at baseline was 66.7 ± 33.2 and reduced to 36.8 ± 41.6 at 6-months and 26.1 ± 33.2 at 12 months. Pain medication was significantly reduced and QBPDS improved from 59.2 ± 12.2 at baseline to 44.1 ± 13.7 at 12 months. Five patients returned to work and overall patient satisfaction at the end of the study was high.

- In 2020, Mekhail, *et al.* published results from a randomized, double-blind, controlled EVOKE trial with outcomes evaluated results at 6-months (n=125) and 12-months (n=118).[xxx] The primary outcome was achieved in a greater proportion of patients in the closed-loop SCS group than in the open-loop SCS group at 3 months (51 [82.3%] of 62 patients vs 38 [60.3%] of 63 patients; a difference of 21.9%, (95% CI 6.6-37.3; p=0.0052) and at 12 months (49 [83.1%] of 59 patients vs 36 [61.0%] of 59 patients; difference 22.0%, 6.3-37.7; p=0.0060). No differences in safety profiles were observed between the two groups. Few post-operative complications were observed and resolved. Twenty-four-month results sustained high rates of response (>80% pain reduction). Another publication describing the reduction in opioid use in this population by Brooker, *et al.* found that 82.8% of patients with baseline opioid use had their use eliminated or reduced.[xxxi]

- In 2020, North, *et al.* published outcomes from their multi-center, prospective, randomized controlled trial evaluating sub-perception SCS (n=140).[xxxii] Subjects were

implanted 3.8 ± 2 years previously and had a disability score (Oswestry Disability Index) of 70.2 ± 11.4 at study start. Of the randomized subjects that completed the End of Period 2 Visit, 93 (66%) preferred sub-perception SCS and their mean overall pain was reduced from 7.3 ± 1.1 (N = 89) at baseline to 4.0 ± 2.1 (N = 80) at 12-months post-activation. Post hoc analysis also demonstrated that multiple options provided superior outcomes, as supported by a 74% increase in the responder rate when subjects could choose their most effective option (47%), compared with supra-perception alone (27%). This is just one example of personalized care unique to patient functional needs and management objectives. The investigators affirmed long-term safety of SCS.

- Breel, *et al.* evaluated 32 patients with chronic neuropathic leg pain after back surgery (FBSS) to start 1000 Hz or 30 Hz stimulation programming for nine days, followed by a five-day washout and crossover to the other programming option for another nine days.[xxxiii] During the crossover period there was no statistically significant difference in pain scores across the 1,000 and 30 Hz groups. Pooled results showed 47% of patients achieved more than 80% pain improvement at the 12-month follow-up.

- In 2021, Fishman, *et al.* compared differential target multiplexed SCS (DTM-SCS) to traditional SCS for chronic low back and leg pain.[xxxiv] In this prospective, randomized, post-market trial (n=128, 94 implanted subjects following SCS trial at 12 U.S. centers), investigators reported low back pain responder rates of 80.1% with DTM-SCS that were superior to 51.2% with traditional SCS (p = 0.0010). Mean low back pain score reduction was greater (5.36 cm) with DTM-SCS than reduction (3.37 cm) with traditional SCS ($p < 0.0001$). These results were sustained at 6- and 12-months. Safety profiles were confirmed regardless of which technology was used.

- Also in 2021, Metzger, *et al.* reported outcomes using fast-acting sub-perception therapy (FAST).[xxxv] Mean overall pain score at baseline was 8.4 ± 0.2 (n = 41). After activation of FAST, a 7.1-point reduction in overall pain score was (1.3 ± 0.2, $p < 0.0001$) reported within 11.2 ± 1.9 minutes (n = 34). This decrease in pain score was sustained out to a 3-month (1.6 ± 0.3, n = 26) and 6-month follow-up (1.7 ± 0.4, n = 18). At the last follow up (mean = 223 ± 132 days), a pain score of 1.6 ± 0.3, n = 30 was reported.

- Two-year outcomes from the Petersen, *et al.* study of HF-SCS in diabetic peripheral neuropathy (DPN) were published in 2023.[xxxvi] At 24 months, 10 kHz SCS reduced pain by a mean of 79.9% compared to baseline, with 90.1% of participants experiencing ≥50% pain relief. Participants had significantly improved HRQoL and sleep, and 65.7% demonstrated

clinically meaningful neurological improvement. Five (3.2%) SCS systems were explanted due to infection. Over 24 months, 10 kHz SCS provided durable pain relief and significant improvements in HRQoL and sleep. Furthermore, the majority of participants demonstrated neurological improvement. These long-term data support 10 kHz SCS as a safe and highly effective therapy for PDN.

- Finally, in 2023, Wallace *et al.* reported sustained functional improvements in the COMBO randomized controlled trial.[xxxvii] In that study, 88% of those receiving combination therapy and 71% with monotherapy alone reported a ≥50% decrease in overall pain without an increased dose of opioid drugs at 3-months after start of therapy. This responder rate was found to be 84% at 1-year and 85% at 2-years. Analysis of functional activities or disability showed that patients improved from 'severely disabled' at study start to 'moderately disabled' after 2-years, indicating that effective, long-term (2-year) improvement can be achieved using SCS-based combination therapy for chronic pain.

Request: We, respectfully, request that the above nine peer-reviewed publications be included in the Draft Rereview. Limiting the Draft Rereview to only studies comparing SCS to CMM or repeat spinal surgery excludes much of the more recent clinical literature and several important RCTs that describe recent enhancements of SCS technology. Also, the report should address the full body of RCTs and real-world evidence that has improved outcomes because of rapid advances in hardware, software, firmware, and patient selection. We understand that taking these steps requires that the months-long process of synthesizing the assessment will need to be, for all practical purposes, repeated. Following this request requires that the current Draft Rereview is rejected.

B. Strength of Evidence ("SOE") with GRADE Criteria

We are also concerned that certain studies continue to be included in the literature review despite our repeated objections that they contain very serious, even "fatal" flaws.

Our largest such concern is the inclusion of Hara, *et al.* in the Draft Rereview despite our numerous objections.[xxxviii] Our primary concern with this trial is that the SCS stimulation algorithm used was **known to be ineffective by the clinical community prior to the start of the study and would never be used by clinicians in the State of Washington.** This was essentially a placebo versus placebo study that showed the expected results. The results were as expected; however, the Draft Rereview concludes that this study shows SCS was ineffective rather than that the study was "fatally" flawed in a unique manner.

The Hara, *et al.* publication triggered a reaction from leaders in the field of neuromodulation, resulting in a peer-reviewed rebuttal article, Eldabe, *et al.*, that was published in *Pain Practice*.[xxxix] Again, in the spirit of "sound clinical judgement" the specifics of the rebuttal are offered below:

- The choice of SCS waveform in this story was at the very least "unusual" given the authors, using their own defined protocol, specified using a five-spike burst (BurstDR) that is known to be effective; however, the authors actually applied, a four-spike burst at 50-70% of a paresthesia perception threshold, without providing an explanation for the change from protocol. **This combination of programming settings had previously been shown to be equivalent to sham, and are not used in routine clinical practice, and are not recommended by the manufacturer.**
- Authors performed a trial period with tonic stimulation (i.e., not the same settings as used in fully implanted patients). Further, patients advancing to a full implant had a reduction of at least 2-points for leg pain, yet this deviated from the protocol definition of a successful trial as a ≥30% in pain reduction. A 2-point reduction does not necessarily equate to a 30% reduction. Finally, the threshold of a ≥30% reduction in pain during the trial phase does not correspond to the international guideline recommendations of a ≥50% reduction in pain.
- An SCS device is like a pacemaker. If a patient's pain does not respond to the initial settings, the SoC in the US is to adjust the programming of the SCS device. In this study, no attempts were made to adjust the programming in patients who did not respond to SCS at the initial settings.
- We fail to understand how AAI can consider this a high-quality study when the methods used to ensure blinding of the sham study arm were not reported in the manuscript, protocol, or trial register, therefore it is not possible to evaluate if participants remained blinded.

We believe that the unusual pattern of facts regarding Hara, *et al*. would constitute "Significant flaws in this study that imply biases of various kinds that may invalidate results." This study contains "fatal flaws" in design, analysis or reporting" (p. 67) which should mean that it is classified as "Poor." However, this study is classified as "Good" on p.76 in the Draft Rereview.

Another important example of SOE misclassification is Hollingworth, *et al.* This is an economic analysis that simply adds an economic analysis on top of the clinical study performed by Turner, *et al.*[xl] Turner, *et al.* has several SOE issues; it lacks randomization which dramatically weakens it; most importantly, it does not follow the current guideline-directed SoC (for instance, patients did not undergo psychological evaluation pre-implant); and it is unique among studies in using the approach that all patients who underwent placement of a trial SCS were analyzed (n = 51). Only

27 patients (53%) had a successful trial as opposed to >83% identified in more recent studies;[x i] however, the analysis of patients who did not have a permanent SCS implanted were included in the SCS limb, unlike more recent SCS clinical studies. For reasons including non-randomization of subjects, failure to follow current clinical practice guidelines, poor effectiveness of trial SCS, and non-standard statistical approach, Turner, *et al.* was found in the Draft Rereview to have a "low" SOE on all clinical endpoints except mortality for which it was found to be "insufficient." For the above reasons, we agree that their results do not describe the performance of SCS, let alone the performance of SCS in 2023. Our concern comes when Hollingworth, *et al.* builds upon this weak, "low quality" clinical data set and creates an economic analysis/cost-effectiveness study and is determined in the Draft Rereview to be a "good quality study (QHES 90/100)" (p. 120).[xlii] The authors of the QHES instrument which AAI utilizes to grade economic analyses write:

> "On the most basic level, cost-effectiveness evaluations and other economic analyses should be methodologically sound, clinically oriented, and policy relevant."

Our concern remains that the approach taken inflating the SOE of the Hollingworth, *et al.* economic analysis in the Draft Rereview is none of these, despite numerous attempts to provide "sound clinical judgement." Hollingworth, *et al.* does not describe the current economic performance of SCS because Turner, *et al.* does not describe the current clinical performance of SCS.

> **Request:** We respectfully request that the Hara, *et al.* publication is deleted from Draft Rereview and make updates to the entire analysis based on that deletion. If that cannot be done, then we believe that the Committee must reject the report. Also, we respectfully request that Hollingworth, *et al.* be classified no higher in terms of SOE than is Turner, *et al.*, and we agree that Turner is appropriately classified as "low."

C. Role of Technology Assessments in the Draft Rereview.

There are significant issues with two of the technology assessments presented in the Draft Rereview.

Additionally, O'Connell, *et al.* are authors of a Cochrane review and meta-analysis of 15 RCTs.[xliii] They reached flawed conclusions regarding SCS for the reasons outlined in a letter to the editor by Russo, *et al.* published in *Neuromodulation*.[xliv] The key points of Russo, *et al.* included:

- Serious ethical concerns with maintaining patients on a placebo/sham arm without the option of crossover in a patient population with severe refractory pain. However, the meta-analysis did not include large, randomized trials with a crossover design, such as PROCESS [xlv]and PROMISE [xlvi] because they did not meet the Cochrane definition of

"randomized." All randomized controlled trials should have been included, even those at risk of bias and they should include a notation of the presence of bias, but not excluded altogether from the analysis.

- Authors on the meta-analysis had no experience with neuromodulation, which introduces failure to appropriately interpret the literature, namely the exclusion of RCTs designed to compare the new waveforms against standard/tonic SCS. By excluding these trials, the O'Connell meta-analysis excluded trials that included long term (two-year) follow-up.
- Conclusions on cost-effectiveness and frequency of adverse events were summarized without comparison to the alternatives (surgery and opioids); where the comparators have their own inherent risks and costs.

Traeger, *et al.* is the second Cochrane review and meta-analysis of 13 randomized controlled trials that similarly had flawed conclusions [xlvii] that are outlined in a published critique by Durbhakula, *et al.*[xlviii] published in *Pain Medicine*. Key points in this critique included:

- While placebo/sham studies are the highest level of scientific evidence, they are impractical to execute in the real world of SCS, with investigators struggling to complete them due to expense and difficulty in recruitment.
- Authors removed one of the three main randomized controlled trials evaluated, reporting that the Kapural *et al.*[xlix] study introduced too much heterogeneity based on the I2 statistic. However, the I2 statistic is a calculation that is only appropriate for large meta-analyses and difficult to justify applying when there are only three studies in the analysis.
- Conclusions on SCS probable lack of efficacy are based on the inclusion of the Hara et al[l]. randomized trial that was published on October 18, 2022, despite the authors' search specifications, including ongoing trials only up to June 10, 2022. This raises questions on the conduct of the systematic review process. Further, the authors did not mention flaws in this RCT design.

We suggest that the following review be included in the Draft Rereview. This seems to have been excluded for reasons that we cannot understand, as our understanding is that it seems to meet the criteria for inclusion.

In 2022, Ho *et al.* published their meta-analysis of randomized controlled trials in complex regional pain syndrome.[li] Four randomized controlled trials, including SCS, were identified for the treatment arm for CRPS: one study compared low frequency tonic SCS (LF-SCS) versus conventional physical therapy, two studies compared placebo/sham SCS with LF-SCS and a

multitude of waveforms, and one study compared LF-SCS with high-frequency SCS (HF-SCS). Two of the studies were rated as having a low risk of bias, one study was rated as having some concerns for bias, while the final study was rated as having a high risk of bias. A meta-analysis of four studies comparing conventional therapy/placebo SCS stimulation against LF-SCS revealed an increased benefit of LF-SCS in pain reduction up to a month (mean difference [MD] = -1.17 points; 95% CI = -1.61 to -0.73; $p < 0.001$, I2 = 42%). Another meta-analysis of 2 studies showed that LF-SCS results in higher global perceived effect scores relative to conventional therapy/placebo SCS stimulation (MD = 1.58; 95% CI = 1.00 to 2.15; $p < 0.001$, I2 = 0%). The researchers concluded that LF-SCS is superior to conventional therapy/placebo SCS stimulation.

Request: We respectfully request that the two above Technology Assessments currently included in the Draft Rereview (O'Connell and Traeger) are biased and should be deleted. At a minimum, the issues pointed out by Russo and Durbhakula must be addressed to minimize bias. Without the above actions being taken, we recommend that the Committee reject the Draft Rereview. We suggest that Ho may be added to this section as an unimpeached alternative.

D. Spinal Cord Stimulation Proven Cost-Effective

Across several commercially available technology platforms and waveforms, SCS has been consistently shown to be cost-effective using globally recognized methodologies. The Original WSHCA Report on SCS found it to be moderately cost-effective based on a UK study that found the ICER to be "moderate" at <$20,000/QALY. (Original Report p. 7) The clinical literature since 2010 contains a number of articles describing the cost effectiveness of SCS when compared with standard willingness-to-pay thresholds.

- Duke University researchers evaluated health care utilization for SCS compared to CMM in subjects diagnosed with FBSS.[lii] 122,827 subjects, including 5,328 SCS patients (4.34%), were evaluated from 2000 to 2012. Total costs decreased following SCS implantation at 1-, 3-, 6- and 9-year time points. The significant and sustained decrease in cost (-68%) proved SCS as cost effective for this population, compared to CMM [CR: 0.32; 95% CI 0.24, 0.42 p <0.001]. Although SCS implantation results in an initial incurred cost from the procedure, annual costs were significantly reduced in the 9-year period following SCS implantation.

- In 2017, Hoelscher *et al.* evaluated published cost analyses.[liii] Five studies performed cost-effectiveness analyses and found that results fell within usual third-party "willingness-to-pay" thresholds of $50,000 to $100 000 [$USD] quality-adjusted life-years gained.

Information about long-term cost-effectiveness was limited mainly to modelling direct cost data, but durability of SCS treatment suggests that initial costs can be recovered within two-to-three years. Authors concluded SCS was clinically effective in delivering treatment to patients with chronic neuropathic back and limb pain otherwise refractory to traditional medical and surgical options.

- In 2022, Patel, *et al.* evaluated high frequency stimulation (10 kHz) SCS (HF-SCS) finding it to be cost-effective versus CMM through an RCT (n=159, randomized 1:1).[liv] Refractory back pain patients with no prior surgery when treated with HF-SCS realized a significant advantage to the comparator group at 6- and 12- month follow-up. The ICER was calculated including all HCU and medications, except for the initial device and implant procedure, and cost-effectiveness was analyzed based on a willingness-to-pay the threshold of < $50,000 per QALY. Treatment with HF-SCS versus CMM resulted in a significant improvement in QOL (EQ-5D-5L index score change of 0.201 vs -0.042, p < 0.001) at a lower cost, based on reduced frequency of HCU resulting in an ICER of -$4,964 at 12 months. The ICER was -$8620 comparing the 6 months on CMM with post-crossover on 10-kHz SCS. Treatment with HF-SCS provides higher QOL at a lower average cost per patient compared with CMM. Assuming an average reimbursement for both the device and procedure, HF-SCS therapy is predicted to be cost-effective for the treatment of NSRBP compared with CMM within 2.1 years.

- In 2021, Rojo, et al. built upon the cost-effectiveness data with a description of the economic performance of SCS versus CMM in Spain in the setting of FBSS.[lv] Leveraging patient-level real world data from a two-year real-world study of subjects diagnosed with FBSS and who were treated with SCS or CMM, ICERs were estimated in terms of direct clinical cost and QALYs. Costs from the Spanish National Health Service (NHS) perspective were estimated in terms of 2019 Euros. They applied a yearly discount rate of 3% to both costs and outcomes and performed a probabilistic sensitivity analysis using bootstrapping. After 2 years, the health-related QoL measured by the EQ-5D displayed greater improvements for SCS patients (0.39) than the improvements in CMM patients (0.01). The proportion of SCS patients using medication fell substantially, particularly in opioid use (-49%). In the statistical model projection, compared with the CMM group at year 5, the SCS group showed an incremental cost of €15,406 for an incremental gain of 0.56 0.56 QALYs, for an ICER of €27,330/QALY, below the €30,000/QALY willingness-to-pay threshold for Spain. SCS had a 79% probability of being cost-effective.

- In 2015, Italian researchers found SCS to be cost-effective within their health system.[lvi] These data are relevant to WSHCA given that the results associated with SCS are reproducible across different health system archetypes and geographies.

The one outlier in this economic literature seems to be Hollingworth, *et al.* which, as described above, was markedly flawed by its dependence on the flawed Turner, *et al.* study. The poor cost-effectiveness ($131,146 per patient achieving primary outcomes) is directly related to the poor clinical performance of SCS in Turner, *et al.* The low effectiveness of SCS (5%) in this study has been appreciated as an outlier result for over a decade.

As a systematic component of every technology review, WSHCA reviews cost-effectiveness data, presumably, to judge the cost-effectiveness (ICER) of products and services. It is unclear what criteria were used in answering Question 4 above. For context, a recent review of the topic of how health economics informs health care decisions by Kim and Basu reports that ICERs in the $100,000 to $150,000 per QALY range are typical in the US.[lvii]

> **Request:** When making policy decisions based on health economics, it is important for a public body to be transparent about its decision-making process. We respectfully request that WSHCA provide us, in the spirit of transparency of process, with the ICER value threshold that it uses for making decisions based on the cost-effectiveness data presented in answer to Question 4. Additionally, we request, as above, that Hollingworth is given a SOE rating no better than Turner, *et al.* and that the new cost-effectiveness data are included in the Draft Rereview.

VI. Our Conclusions & Recommendations

We sincerely appreciate the opportunity to offer our comments following review of the WSHCA September 1, 2023, Draft Evidence Report on SCS, performed by AAI. While we applaud WSHCA for launching this effort, we believe that the Draft Rereview is deeply flawed, and it would be a mistake for the Committee to accept this report or to act upon it without the radical changes that we have described and requested above.

While our societies and our members have repeatedly attempted to provide “sound clinical judgement” as our input to the process, we have reached the point where the SCS care that we know has been shown to be a safe, effective, and cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates is unrecognizable to us in the Draft Rereview. As a result, we cannot, as much as we would like, agree that the analysis used in the Draft Rereview has any clinical validity. At the present time, clinical response rates routinely exceed 80% in clinical trials of SCS devices with novel algorithms that the process refuses

to accept. By contrast, this process seems to have given enhanced weight to the thirteen-year-old Hollingworth, *et al.* study of Washington Workers' Compensation patients. The low 5% response rate for SCS in that study is an outlier versus other published SCS studies. Moreover, data from this Workers' Compensation population should not be applied to a health benefits population. Along the way, the Draft Rereview at the very least understates, but we think it is fair to characterize it as misrepresenting to the Committee that the current position of the WSHCA to not extend coverage to SCS is in contradiction to **all the Published Clinical Guidelines on SCS (Table 3) and that WSHCA health plans are the only health plans in the US that do not extend coverage to SCS** (Table 6).

Other commenters will no doubt ask you to cover one SCS product or another. Those requests are appropriate and should be understood in a broader context. Our position is that you must fix this Draft Rereview and that you must fix your process for developing future reports to the WSHCA. The Committee deserves better support in its difficult decision-making process than what the Draft Rereview in its current form provides.

If we can be of any further assistance between now and the November 17 meeting, please do not hesitate to reach out to Keri Kramer at [redacted]

Submitted on behalf of the more than 95,000 members we represent,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Anesthesiology
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology

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From: [redacted]
To: htap@hca.wa.gov; HCA ST Health Tech Assessment Prog
Subject: Letter of support for SCS coverage by workers comp
Date: Thursday, September 28, 2023 10:25:56 AM
Attachments: Workers Compensation Opioid Burden Comments to Washington HCA (September 2023).docx

External Email

Attached is my letter of support for SCS as a covered benefit under workers compensation and state insurance plans.

Christina Julian, MD
Anesthesiology and Interventional Pain Management

Acute & Chronic Pain Therapies
[redacted]

PERIOPERATIVE & REGENERATIVE
ACUTE PAIN THERAPIES

Acute Pain Therapies
[redacted]

September 28, 2023

Sue Birch, Director
Washington State Health Care Authority
Cherry Street Plaza, 626 8th Avenue SE
Olympia, Washington 98501

Sent To: shtap@hca.wa.gov

RE: SPINAL CORD STIMULATION HEALTH TECHNOLOGY ASSESSMENT
EQUITABLE ACCESS TO FDA-APPROVED OPIOID ALTERNATIVES

Dear Ms. Birch:

Patients suffering from chronic pain, who are refractory to conservative medical management, remains a significant burden for our State of Washington. This includes injured workers relying upon the State for timely access to medically necessary care. Strong evidence of safety, efficacy and impact on return-to-work exists and should be well considered by the Agency in its current evaluation of spinal cord stimulation (SCS).

1. FDA Approved Opioid Alternatives

According to the United States Centers for Disease Control & Prevention (CDC), 32% of workers' compensation claims with prescriptions had at least one prescription for opioids[1]. Comparatively, the State of Washington reported 42% of workers with compensable back injuries received an opioid prescription, with 16% still receiving opioids one year after injury. The State's report noted even stronger potencies and larger doses are prescribed for musculoskeletal injuries[2]. The State requires physicians exhaust alternatives to opioids though disallows consideration of FDA-approved stimulators that have been proven to reduce or eliminate opioids for chronic pain patients.

The Washington State Agency Medical Directors' Group (AMDG) reported early use of opioids in the workers' compensation population increased the risk of disability[3]. Discontinuation of opioids following three months of use results in long-term dependency on these drugs[4]. Preventing a transition from acute and subacute pain to chronic pain and disability could have a significant impact on protecting productive lives[5]. Indeed, Washington State workers compensation opioid guidelines has resulted in substantial decrease in morphine equivalent[6] but this has likely resulted in additional suffering and undertreatment. Enabling access to FDA-approved devices proven to reduce or eliminate opioids is warranted.

Pre-implant care plans have proven successful when considering SCS. Clearly defining patient expectations and use of opioids pre- and post-implant is an important function of the interventional pain expert. For example, Smith (2022)[7] summarized pre-implant opioid use and outcomes finding initiation of SCS at a preimplantation opioid dose of ≤20 to ≤42.5 morphine milligram equivalents increases the likelihood of post-implantation elimination of opioid use. Additional research is available that details long-term impact of SCS on morphine equivalents stratifying patient groups by clinical characteristics and comorbidities.
Management of pain, using SCS for FBSS, CRPS I and II, will change the trajectory of disability in Washington. Doing so is consistent with published evidence and recommendations by national health authorities. The U.S. HHS Pain

Management Inter-Agency Task Force Recommendations[8] include SCS based upon five Level I studies[9] as well as a body of evidence demonstrating safety, efficacy and long-term durability of treatment effect. SCS was recommended singularly, or as part of a multimodal approach to the management of pain [§2.4 Interventional Procedures, pp. 40 et seq]. Adoption of FDA-approved alternatives to opioid use by the State aligns with Federal, State, and commercial insurance programs to which Washington policymakers may look for guidance.

2. SCS Impact on Workers Compensation & Return to Work

The value of SCS in the disability or workers compensation population has long been established around the world. Sundaraj (2005)[10] examined Australian patient records of 138 patients between 1995 through 2002. One hundred and three (74.7%) patients achieved a greater than 50% reduction in their pain through trial and proceeded to permanent implantation. At one-year following permanent implantation, 84.4% of these still had a reduction in their pain by greater than 50%. Most patients (59.1%) stated their analgesia was good (pain reduction: 50–74%). All patients required opiate analgesics prior to SCS implantation but fell to 54.6% after SCS implantation. Additionally, 73.6% had a significant improvement in their ability to perform activities of daily living and 24% of patients were able to return to work.

Those insured through Washington State programs will benefit from timely SCS once medical management has failed to deliver adequate results. Kumar et al (2014)[11] reported SCS success rates of 47% when chronic pain continued beyond 5.45 years. By comparison those patients who received SCS within two-years reported success rates >80%. Rizvi et al (2014)[12] observed early use of SCS will promote functional restoration, resulting in improved return to work rates.

Published in 2018, Moens et al. delivered their meta-analysis including seven high-quality, peer reviewed and published articles[13]. Pooled outcomes favored SCS use in workers compensation patients. Interventions including SCS resulted in a significantly higher prevalence of patients at work compared with before treatment [odds ratio (OR) 2.15; 95% confidence interval [CI], 1.44–3.21; $I2 = 42\%$; $p < 0.001$]. SCS treatment also results in significantly high odds to return to work [OR 29.06; 95% CI, 9.73–86.75; $I2 = 0\%$; $p < 0.001$]. Based on available literature, SCS proved to be an effective approach to stimulate return to work in patients with specific chronic pain syndromes.

Led by Dr. Valerie Dauriac- Le Masson et al (2023)[14], French researchers evaluated 56 FBSS patients who stopped work between 1999 through 2010. They reported on the considerable impact of FBSS[15] on the patient including intensity of pain, psychological consequences, quality of life and professional activity.
Following SCS implantation through a mean of 7.5 years [range: 5-15 years]. The return-to-work rate was 30.5%, with a median recovery time of 5.5 months. Functional improvements and reduction in unemployment were directly attributable to implantation of a spinal cord stimulator. Earlier use of SCS was an independent variable strongly correlated with earlier return-to-work success.

I trust your staff will consider each of these data within its deliberations. Working together for the best interests of each patient, I am confident we will address treatment objectives of the patient as well as policies espoused by the State.

Sincerely.

Christina Julian

Christina Julian, MD
Interventional Pain Physician, Owner and Clinical Director at Acute Pain Therapies

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[9] Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017;158(4):669-681; Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. *Neuromodulation J Int Neuromodulation Soc*. 2018;21(1):56-66; Kapural L, Yu C, Doust MW, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. *Anesthesiology*. 2015;123(4):851-860; 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;132(1-2):179-188; and 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; discussion 106-7.

[10] Sundaraj SR, Johnstone C, Noore F, Wynn P, Castro M. Spinal cord stimulation: a seven-year audit. J Clin Neurosci. 2005;12(3):264-70.

[11] Kumar K, Rizvi S, Nguyen R, Abbas M, Bishop S, Murthy V. Impact of wait times on spinal cord stimulation therapy outcomes. Pain Pract. 2014;14(8):709-20.

[12] Rizvi and Kumar. Spinal cord stimulation for chronic pain: the importance of early referral (editorial) Pain Manag. 2014;4(5):329-31.

[13] Moens M, Goudman L, Brouns R, Valenzuela Espinoza A, De Jaeger M, Huysmans E, Putman K, Verlooy J. Return to Work of Patients Treated With Spinal Cord Stimulation for Chronic Pain: A Systematic Review and Meta-Analysis. Neuromodulation. 2019;22(3):253-261..

[14] Dauriac-Le Masson V, Gatt MT, Chekroun C, Turak B, Djian MC. Spinal cord stimulation and return to work of patients with failed back surgery syndrome. Pain Pract. 2023;23(5):493-500. See also ePub assessments by Abd-Elsayed and Gilligan (2023) at: Abd-Elsayed A, Gilligan C. Spinal cord stimulation can enhance return to work. Pain Pract. 2023;Epub ahead of print.

[15] Failed Back Surgery Syndrome (FBSS) is describes patients with persistent low back pain, with or without sciatic pain, after one or more spinal surgeries.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Coverage of SCS in Washington
Date: Friday, September 29, 2023 7:51:49 PM

External Email

Washington State HTA,

I recently relocated from San Diego to Washington for work. We were routinely placing cervical and thoracolumbar spinal cord stimulators with great results in patients with radicular pain, diabetic peripheral neuropathy, and CRPS. I understand that you are currently reviewing the supporting evidence and so I will not go into detail here. Please reconsider your prior decision, and cover this very effective treatment for chronic pain patients in the state of Washington. Thank you!

Very respectfully,

Paul DeJulio, MD

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation
Date: Monday, October 2, 2023 1:08:51 PM

External Email

Dear esteemed members of the board;

Please include spinal cord stimulation as an option to patients in chronic pain.
This has been a life saver to many patients who were destined to live in chronic pain.
In our great nation, more than 100,000 people die annually from drug overdose. Many of those patients are reaching out to elicit drugs to address a variety of pain issues.

Please don't block those patients' access to one of the best treatment modalities that medicine has to offer.

I appreciate you it taking my request into consideration.

Sincerely,
Sam Elghor MD
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS
Date: Saturday, September 2, 2023 9:21:08 AM

External Email

To whom it may concern:

It is a travesty that SCS is not covered by Washington State insurance entities. SCS is the standard of care for Failed Back Surgery Syndrome, CRPS, Diabetic Peripheral Neuropathy and other radicular pain syndromes. Washington has the worst coverage of any state. Fireman, Policeman, Teachers and other vital state employees, injured workers, and Medicaid patients do not have appropriate access to non-opioid therapies in our state. This in itself has lead to more opioid prescriptions and opioid over dose deaths in our state. As an interventional pain physician, my hands are tied in terms of options for these patients. There is even new, quality, level one evidence to support the use of SCS for multiple chronic pain diagnoses. In addition, multiple other proven therapies for chronic pain are not covered by Washington State insurances.

I urge the Washington State HCA to cover SCS and other non-opioid therapies for chronic pain.

Best Regards,

John Hatheway, MD
Northwest Pain Care
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for Spinal Cord Stimulation as a Treatment for Chronic Pain
Date: Monday, October 2, 2023 2:08:39 PM

External Email

Dear Members of the Washington State Healthcare Authority,

I am writing to express my strong support for the inclusion of Spinal Cord Stimulation (SCS) as a viable treatment option for individuals suffering from chronic spinal pain. Recent scientific studies have shed light on newly discovered indications, particularly for diabetic peripheral neuropathy and unspecified low back pain, with specific SCS brands such as Abbott and Medtronic demonstrating promising results in these areas.

However, I must bring to your attention certain concerns regarding the recent WSHCA report on SCS, released on September 1, 2023. It has come to my attention that the preparation of this report did not involve medical doctors (MDs or DOs). This absence is significant, as the expertise and clinical insight of physicians are critical in understanding the implications of these studies and their importance in the field of clinical medicine. There are nuances in patient care and medical decision-making that only a licensed physician can truly grasp.

Furthermore, it is important to acknowledge that the report, being prepared by the state of Washington itself, may carry inherent biases. Financial considerations inevitably come into play when evaluating the cost-effectiveness of medical interventions, but it is crucial that this does not unduly influence the availability of potentially life-changing therapies like SCS. It is imperative that the evaluation process remains objective and prioritizes the best interests of patients.

I would also like to bring to your attention that Washington State stands out as the only state or territorial entity in both the USA and western Europe that places restrictions on SCS beyond what insurance will cover. Presently, under most private insurance plans in this state, SCS is limited to failed back surgery syndrome and complex regional pain syndrome (CRPS). The fact that the limitation exists in this state in the first place and it is the result of a prior evaluation by WSHCA, shows that the primary function of reports like the one about SCS prepared by WSHCA is to place extra limits on care.

In conclusion, I urge the Washington State Healthcare Authority to reexamine the current restrictions on SCS and consider the latest scientific evidence that supports its effectiveness in addressing chronic spinal pain, particularly in cases of diabetic peripheral neuropathy and unspecified low back pain. It is essential that the evaluation process involves the expertise of licensed medical doctors to ensure a comprehensive understanding of the implications of these studies.

Thank you for your attention to this important matter. I look forward to seeing continued progress in improving access to effective pain management options for individuals suffering from chronic spinal pain.

Sincerely,

Nicholas Juan, MD
Interventional Pain Management
Peninsula Pain Clinic

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: To HCA/HTCC: Regarding Spinal Cord Stimulation
Date: Sunday, October 1, 2023 4:39:36 PM

External Email

To Washington State Health Care Authority (HCA) and Health Technology Clinical Committee (HTCC):

We are writing this letter in support of the use of spinal cord stimulation (SCS). We are speaking as physicians who take care of chronic patients on a daily basis.

We are deeply saddened that the state of Washington/HCA/HTCC does not support members of their state including teachers, firemen and women and policemen and women who have selflessly served when it comes to chronic pain management. There is robust evidence supporting the use of spinal cord stimulation (SCS) in the treatment of nonsurgical back pain, diabetic neuropathy, post-laminectomy syndrome, and intractable leg pain, among others. Our understanding is that the initial decision made by the HCA was based on an older study, using older technology and technique, on a subset of patients that was poorly representative of the type of patients that this treatment mostly addresses. In reality, these patients are often not "major surgical" candidates due to many factors including patient health conditions, age, or surgical complexity among many other reasons. Spinal cord stimulation is a treatment that can make a marked improvement in not only pain, but also improve function and quality of life in these patients.

Since the decision made by the HCA, over a decade ago, SCS has seen quite a number of new advancements as well as seen new companies enter the field of spinal cord stimulation. High frequency stimulation, burst stimulation, newer programming algorithms and newer devices have markedly changed the treatment approach, and patients are now able to have much more effective chronic pain management as a result. The Centers for Medicare & Medicaid Services (CMS) has updated their Medicare Coverage Database (MCD) and Noridian has updated the Local Coverage Determination (LCD) for spinal cord stimulation within the last several years for spinal cord stimulation. Newer evidence has been published and as a result, the indications for spinal cord stimulation have increased with the treatment being expanded by the United States Food and Drug Administration (FDA).

SCS and neuromodulation are approved for treatment by Medicare, the Veterans Administration, as well as numerous commercial insurances in Washington State. We believe it is a travesty that this is not offered to the those in Washington State that are covered under the Washington State Health Care Authority.

We strongly request that the Washington State HCA and HTCC update the policy on spinal cord stimulation, and decide to reinstate this treatment for the patients covered under the Health Care Authority.

Sincerely,
Daniel Kwon, MD
Board Certified Physical Medicine & Rehabilitation
Subspecialty Pain Medicine
MultiCare Yakima Memorial Specialty Medical Director

Joe Kim, MD
Board Certified Anesthesiology
Subspecialty Pain Medicine
MultiCare Yakima Memorial Physician Lead for Pain Medicine

Henry Kim, MD
Board Certified Physical Medicine & Rehabilitation
Subspecialty Pain Medicine
MultiCare Yakima Memorial Physician

Thomas Gedulig, DO
Board Certified Anesthesiology
Fellowship training in Pain Medicine
MultiCare Yakima Memorial Physician

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comments for Report
Date: Sunday, September 10, 2023 6:11:57 PM

External Email

To whom it may concern,

I would like to comment on the importance of permitting SCS coverage for patients in Washington state. It is a vital treatment which is often the last viable option for patients with refractory types of pain. While the recent Cochrane database studies (O'Connell, Traeger) have expressed concerns over study quality in SCS RCTs, these meta-analyses themselves have been the subject of critiques re: methodology (Russo et al. 2023). Overall, SCS is a widely-used treatment option for patients with severe, intractable pain; while research is still needed regarding optimal indications and patient selection, it is important to offer this therapy overall.

Yian

--
Yian Chen
Assistant Professor
University of Washington

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS HTA response letter from PSPS
Date: Thursday, September 28, 2023 11:37:11 AM
Attachments: HTA Letter (1).docx

External Email

Thank you for your consideration.

Pacific Spine & Pain Society

PACIFIC SPINE PAIN SOCIETY

Washington State Health Technology Assessment Committee,

The Pacific Spine and Pain Society is a society of physicians from multiple medical specialties who are joined with the common mission of supporting collaboration and excellence in the treatment of patients with spine pain. This Society achieves this through education of providers, advocacy and research.

Chronic neuropathic pain is a highly prevalent and exceedingly difficult condition to treat. The causes of such include persistent pain after spinal surgery, refractory lumbar radicular pain, complex regional pain syndrome, peripheral neuropathy & arachnoiditis. It is the charge of pain management physicians to care for patients who suffer with these conditions. Thoughtful providers do with great respect for the substantial body of evidence which recommends against chronic opioids, underlines the limited efficacy of non-opioid pharmacologic options, emphasizes a multimodal approach including attention to pain, function, mood and quality of life. Recognizing the scope of the problem, the Health and Human Services Department has developed the Pain Management Best Practices Interagency Task Force Report (2022).

This approach is reasonably successful for many patients with neuropathic pain, though there are those for whom it falls short. Among those, spinal cord stimulation is a vital treatment for our patients. Spinal cord stimulation has enjoyed remarkable evolution over its >20 year lifespan. This is especially poignant in the past 10 years. With the advent of high-frequency stimulation, burst waveforms, combination therapy including high-frequency with paresthesia-based programming and dorsal root ganglion stimulation, physicians are able to wield this technology in ways that are more personalized to a patient's pain condition. In this same time frame there has also been an explosion of research demonstrating the efficacy, safety and value to patients in regard to improved function, cost-effectiveness, improved mood & reduced opioid use.

Every private insurer in the United States and Centers for Medicare Services have coverage policies which recognize the value of this technology. Additionally, every state in the country has a policy which allows for selective use of spinal cord stimulation – except Washington State.

The Pacific Spine and Pain Society and its membership are wholly committed to advocating for the marriage of science and clinical care. As such, we are formally voicing our disagreement with the Washington State Labor and Industry's unilateral denial of coverage policy concerning spinal cord stimulation. We implore the Health Technology Assessment Committee to strongly consider aligning with the rest of the country's L&I policies, Medicare policies and private insurer policies in allowing

suffering patients to benefit from an evidence-based, longstanding, widely adopted treatment for chronic neuropathic pain.

The Pacific Spine & Pain Society

Board of Directors

Policy & Advocacy Committee

Jennifer M. Lee, MD

Michael Leong, MD

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Spinal Cord Stimulation
Date: Monday, September 25, 2023 2:05:35 PM

External Email

September 25, 2023
To: Members of the Health Technology Clinical Committee
Washington, State
Re: Access by all Citizens of WA State for the use of the Spinal Cord Stimulators

It has been brought to my attention that any patient with insurance covered by the Health Care Authority in Washington State is not covered for spinal cord stimulation under any provision. This is very disappointing and unfortunate news.

While I have always had private health insurance or Medicare insurance with a supplemental medigap policy which I purchase myself, I was unaware that those covered by the HCA of WA State were considered ineligible to be considered for any kind of spinal cord stimulation, as there is no provision for it.

I believe that this is a procedure that must be considered for all.

Recently, I had a spinal cord stimulator trial and then had one implanted permanently into my back. I had a spinal fusion which after 6 plus years was no longer effective in addressing the pain I experienced in my lower back, sciatic pain, and miscellaneous pain throughout my body. I would like to add that I have Rheumatoid Arthritis pain too due to the presence of RA for the past 30 plus years. While I was implanted with the spinal cord stimulator to relieve sciatic pain I am happy to report varying levels of pain relief throughout my entire body. It was and continues to be an amazing change to experience such relief. I no longer need to remain inactive, as I have regained significant use of my hands, arms, legs and feet to the extent that my prescription drug use has declined in treating my pain. I am able to use my legs again and can even sit on the floor for long periods of time to enjoy activities with my 7 and 9 year old grandsons, bathe myself in a standard bath tub, exercise my legs with leg lifts and live a more productive and fruitful life without sciatic pain and through the elimination of some major RA pain. I am also able to cook, bake, sew, quilt and even do household cleaning and yard chores without the use of any additional prescription pain medications. Being unaware of the spinal cord stimulator and the many areas it is designed to target for pain, I was forced to use additional medications.

This device is like a **"well kept secret"** as until my exposure to it for my sciatic pain, I had no idea it even existed. It has been a major life-changing help to me. During the middle of the night, I often experienced random episodes of leg muscle pain/spasms and now I can even sleep through the night without sleeping medications since using the spinal cord stimulator. These are some of the benefits that I have experienced since using the Boston Scientific Spinal Cord Stimulator.

Sincerely,
Mary K. Pullen (age 71)

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Act Now to Support Spinal Cord Stimulation!
Date: Friday, October 6, 2023 11:54:15 AM

External Email

To whom it may concern,

As a wife and mother of three daughters and current Director of Student Services and many years of teaching, I am writing to urge you to support Spinal Cord Stimulation. As an educator/school counselor since 1999 in the state of Washington.

I have unfortunately had a ACDF as well as a PSIF cervical fusion. After a year and a half the pain began again and I have tried physical therapy, massage, accupuncture, muscle relaxers, injections and my next step is to do a trial for spinal cord stimulation. Unfortunately, because I teach in Washington state this is the only state that does not approve SCS. It is very frustrating as I have difficulty sleeping, having to ice in the middle of the night. I love my job, however with ongoing pain I miss work too often to try to keep my pain under control. My quality of life has declined and I am 49. I want to hold my grandchildren one day, but at this time I can't hold babies because of the excruciating pain I get after.
The things I used to love doing have been taken away. If I garden, I will hurt for days, weeks and there is not a medication that works for me. There are too many side effects with the prescriptions I've tried. So between either not working or not wanting to feel side effects, I have to be intentional about how I live my life. My left side of my face, neck, shoulder, arm has not been the same. I have a standing desk at work and other accommodations to help me, however it doesn't take away the pain.

Washington is the only state that does not approve spinal cord stimulation (SCS) for any diagnosis for any patient with insurance covered by the Health Care Authority (about 2.5 million Washingtonians). I have Blue Cross-UMP health insurance and cannot get SCS at this time.

When I began in the teaching career our insurance was excellent and it has declined significantly over the years. I pay for the best coverage and to not be able to at least have the trial to see if it will work is wrong.

Please I urge you to support Spinal Cord Stimulation.

Sincerely ,

Becky Brooks

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SCS coverage
Date: Tuesday, October 3, 2023 1:17:50 PM

External Email

Washington Health Care Authority

Attn: Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712

Re: Draft HTA Report for Spinal Cord Stimulation (SCS)

Dear HTA Review Committee:

I am writing to express my concern about the Committee's current stance on Spinal Cord Stimulation (SCS) as not covered. As a physician who specializes in pain management, I have seen firsthand the benefits of SCS for my patients with chronic back and neck pain. SCS has been shown to be a safe and effective treatment for a variety of chronic pain conditions.

The current draft report relies on an imperfect analysis – through the lack inclusion of some of the highest level RCTs due to lack of conservative medical management comparator despite 2-year durability outcomes. Additionally, none of the durability data from the long-term safety and efficacy from RCTs is being considered in the current report.

The Committee's decision to not cover SCS has a significant impact on patient care. Many of my patients who are eligible for SCS are unable to afford the procedure out-of-pocket. This means that they are forced to continue living with chronic pain and the associated disability.

The Committee's decision also creates a disparity between Washington patients and patients in other states. **All other States cover SCS for chronic pain patients**. This means that Washington patients are at a disadvantage when it comes to accessing effective pain management.

The lack of access to SCS can have a devastating impact on patients' lives. Many of my patients with chronic pain are unable to work, exercise, or participate in social activities. They often experience depression and anxiety.

The Committee's decision to not cover SCS is not only harmful to patients but could have long term socioeconomic impacts on patients. SCS can help to reduce the need for opioids and other pain medications, which can save the healthcare system money in the long run.

SCS can also help to reduce the need for opioids and other pain medications. I would like to add that the lack of access to SCS can lead to increased reliance on opioids for pain management. This is a serious concern, as the opioid epidemic has claimed the lives of hundreds of thousands of Americans in recent years.

I urge the Committee to reconsider its decision and cover SCS for chronic pain patients. It is the right thing to do for our patients and for our community.

Sincerely,

Janmeet Sahota, D.O.

Apex Spine Institute

[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comment on draft evidence report on spinal cord stimulation
Date: Tuesday, October 3, 2023 4:42:51 AM
Attachments: PastedGraphic-4.tiff

External Email

The Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, appreciates the opportunity to submit comments to the Washington State Health Care Authority's (HCA) Draft Evidence Report on Spinal Cord Stimulation (SCS).

For nearly 30 years, MDMA has represented the medical device industry in Washington, DC, supporting policies that promote medical innovation and patient access to lifesaving and life-changing medical technologies. MDMA's membership is broad and diverse, ranging from small start-ups to multinational medical device companies. It is a long and risky venture to develop novel medical innovations, and those that succeed have changed the face of medicine and redefined what is possible in the diagnosis and treatment of deadly diseases like cancer and diabetes and life-altering conditions like chronic pain, spinal cord injury and urinary incontinence.

MDMA appreciated HCA's decision to conduct a re-review of the clinical evidence for coverage of SCS. However, upon review of the draft report, we are discouraged by omissions of important clinical data and we are concerned that this suggests a bias against the efficacy of spinal cord stimulation.

<!--[if !supportLists]-->**A.** <!--[endif]-->**The draft report's review of selected national payer policies and previous HTAs is incomplete and does not reflect widespread coverage of SCS by other payers.**

The summary of prior selected health technology assessments (HTAs) in Table 5 includes two prior HTAs of SCS: NICE 2020 (comparison of closed-loop SCS vs open-loop SCS) and Ontario 2020 (HF10 vs. low-frequency SCS). We are puzzled by the choice to review these two HTAs given the decision in the Population, Intervention, Comparison, Outcomes and Study (PICOS) to only include comparisons to conservative medical management or spinal surgery. If HCA including these HTA designs, why have the randomized controlled trials (RCTs) underlying them been excluded in the main summary of literature? Additionally, the report does not include other US HTAs recently updated on SCS such as ECRI and BCBS Evidence Street, which are widely used by US payers when determining coverage parameters for technologies.

While the national payer policies summarized in Table 6 of the HTA are relevant and correct (CMS national coverage determination, Aetna coverage policy, Cigna payer policy), we question why the review was so limited and specifically does not mention the 49 other state Medicaid programs that cover SCS. In addition, the largest commercial payers in the US by covered lives all have published SCS coverage policies available for review and inclusion – with all affording coverage for at least a subset of FDA-approved indications.

Furthermore, at a minimum, it would seem reasonable to include Washington's the top commercial payers, such as Premera Blue Cross and local Medicare coverage for SCS.

B: Opioid Burden: Disproportionate Impact on Workers Compensation Programs

According to the CDC, 32% of workers' compensation claims with prescriptions had at least one prescription for opioids. Comparatively, the State of Washington reported 42% of workers with compensable back injuries received an opioid prescription, with 16% still receiving opioids one year after injury. Preventing a transition from acute and subacute pain to chronic pain and disability could have a significant impact on protecting productive lives. The State requires physicians to exhaust alternatives to opioids though disallows consideration of FDA-approved stimulators that have been proven to reduce or eliminate opioids for chronic pain patients. Enabling access to FDA-approved devices proven to reduce or eliminate opioids is warranted.

Adoption of FDA-approved alternatives to opioid use by the State aligns with Federal, State, and commercial insurance programs to which Washington policymakers may look for guidance. Using SCS for Failed Back Surgery Syndrome (FBSS), Complex Regional Pain Syndrome (CRPS) I and II and diabetic peripheral neuropathy is consistent with published evidence and recommendations by national health authorities. For example, the U.S. HHS Pain Management Inter-Agency Task Force Recommendations include SCS based upon five Level I studies and a body of evidence demonstrating safety, efficacy, and long-term durability of treatment effect. SCS was recommended singularly, or as part of a multimodal approach to the management of pain [§2.4 Interventional Procedures, pp. 40 et seq].

MDMA urges the Committee to carefully consider all the improvements in this health technology and the evidence of long-term efficacy now available regarding SCS. The technology has advanced significantly since the last review by the Health Technology Clinical Committee in 2010, with improved reduction in disability, pain relief and long-term improvement in quality of life and functionality. Recent controlled trials and reviews have consistently demonstrated improved quality of life with reduced use of opioids, supporting increased return to work and decreased disability.

We hope the committee will take a deeper dive into what has been excluded and come to a reasonable conclusion to add SCS as a covered benefit for the many patients who have waited decades for this treatment option. We believe that a reasonable approach would be to include SCS as a covered benefit with similar criteria to Noridian or other top Washington payers.

We appreciate the opportunity to submit comments and thank you for your consideration. We look forward to engaging in the process as you move forward with this review. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Daniel Waldmann, JD
EVP, Health Policy & Reimbursement
Medical Device Manufacturers Association (MDMA)
[redacted]

Table 4. Responses to Public Comments on the Topic Selection.

	Comments	Commenter(s)	Response
1	The following individuals or healthcare organizations provided experiences with SCS systems from a clinician's perspective.	Individuals Warner Asch Neil Batta Adam Burkey Zach Fisk Jon Geffen Christopher Godbout David Hou Andrew Koogler Jeff McLaren Isuto Nishio David Velling Kathy Wang Ross Vogelgesang Healthcare organizations Daniel Kwon* Lauren Platt McDonald & Steven P. Stanos† (Teddi McGuire)	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
2	The following individuals, academic institutions, device manufacturers, associations, or healthcare organizations made specific requests to the Washington State Healthcare Authority urging them to cover SCS.	Individuals Neil Batta Adam Burkey Zach Fisk Jon Geffen Christopher Godbout David Hou Emilie Jones Andrew Koogler David T. Pitkethly David Velling Kathy Wang Academic institutions Brett Stacey** Device manufacturer David Caraway§ (Sandeep Patil) Associations and societies Karen James‡ Healthcare organizations Lauren Platt McDonald & Steven P. Stanos† (Teddi McGuire)	Comments pertaining to formulation of policy do not require a response by the evidence vendor. The vendor does not suggest, recommend, determine, or evaluate coverage policy.
3	The following individuals or device manufacturer suggested investigation of	Individual Adam Burkey	These comments and suggested citations related

	new SCS systems or suggested head-to-head studies comparing SCS systems.	Device manufacturer David Caraway[§] (Sandeep Patil)	to this were discussed with the HTAP during topic refinement. The program's preference was to keep the scope of the update consistent with that of the prior report. Comparison of different SCS modes of operation, waveforms or frequencies was not part of the final review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS.
4	The following individuals, device manufacturer, or healthcare organization expressed appreciation for the consideration of a re-review.	Individuals Christopher Godbout Emilie Jones Device manufacturer Wendy Chan[††] Healthcare organizations Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	Thank you for the comments.
5	The following individuals, academic institutions, device manufacturer, or healthcare organization shared that painful diabetic neuropathy had recently been approved as an indication for SCS.	Individual Christopher Godbout Academic institutions Brett Stacey[**] Device manufacture Wendy Chan[††] David Caraway[§] (Sandeep Patil) Healthcare organizations Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	Thank you for the comments. Painful diabetic neuropathy was included in the report.
6	The following individuals, academic institution, device manufacturer, or healthcare organizations suggested references as starting points for evidence	Individuals Jon Geffen Ross Vogelgesang Academic institutions Brett Stacey[**] Device manufacture Wendy Chan[††]	The scope of the citations suggested was discussed with the HTAP during topic refinement. All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. Reasons for study

		David Caraway[§] (Sandeep Patil) <u>Healthcare organizations</u> Daniel Kwon[*] Lauren Platt McDonald & Steven P. Stanos[†] (Teddi McGuire)	exclusion at full text are in the appendix.
7	The following individual provided experiences of living with pain treated by SCS systems, the costs from a patient's perspective, or otherwise hoping to one day gain access.	<u>Individual</u> David T. Pitkethly	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.

AAI = Aggregate Analytics Inc.; AHRQ = Agency for Healthcare Research and Quality; HCA = Health Care Authority
HTAP = Health Technology Assessment Program; KQ = Key question; RCT = Randomized control trial; SCS = Spinal cord stimulator.

* Representing a group of physicians at Yakima Valley Memorial Hospital in Yakima, Washington.
† Associated with and/or on behalf of Providence Health.
‡ Associated with and/or on behalf of the North American Spine Society.
§ Associated with and/or on behalf of Nevro Corp.
** Associated with and/or on behalf of the University of Washington.
†† Associated with and/or on behalf of Medtronic.

Hamann, Valerie (HCA)

From: Warner Asch [redacted]
Sent: Monday, August 22, 2022 1:02 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS for Washington Workers- support

External Email

Greetings,

I am a physician assistant working in interventional pain. Patients in chronic pain are limited in treatment options they can receive. This is no exception, when it comes to Labor and industry patients. Indeed, their options are further limited in that interventional procedures are rarely approved, and opioid management is generally restricted by L&I. Indeed, spinal cord stimulation has been proven to reduce opioid dependence in chronic pain patients, more so than other interventions. I see what difficulty these patients have in controlling their pain symptoms everyday. Allowing them access to spinal cord stimulation and other interventions would decrease their reliance on harmful medications, better control their pain symptoms, and improve function overall. I support any effort to make these interventions more accessible.

Sincerely,
Warner Asch, PA-C

Hamann, Valerie (HCA)

From: Hockenson, Kevin [redacted]
Sent: Monday, September 12, 2022 4:11 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS Petition
Attachments: SCS petition -Batta.pdf

External Email

To Whom It May Concern,
We are writing to you to take serious consideration to cover Spinal Cord Stimulator therapies for the 2.5 million Washingtonians.
As a multispecialty spine practice that offer patients conservative therapies, injection and surgery. We have provided care for our community for many decades. With the advancement of spinal cord stimulator and careful patient selection, we have a lot of success with patient who is suffering from post laminectomy pain syndrome, complex reginal pain syndrome and diabetic neuropathy. Based on our data collection, we have about 84% success rate using spinal cord stimulator. Spinal cord stimulator is not a modalities for everyone, but it should be offered to patients with the right diagnosis and the right psychosocial support and wellbeing.
We are privileged to be Washingtonian and should not be denied the same benefit compare to Medicare, other private insurance carriers or other state insurance. We like to offer an effective treatment to all our patients.
We asked the committee to review the scientific data and reconsider for the coverage of spinal cord stimulator based on new clinical studies and physicians feedback.

Thank you,
Neil Batta, MD
Neil Batta, MD
Neospine
[redacted]

To Whom It May Concern,

We are writing to you to take serious consideration to cover Spinal Cord Stimulator therapies for the 2.5 million Washingtonians.

As a multispecialty spine practice that offer patients conservative therapies, injection and surgery. We have provided care for our community for many decades. With the advancement of spinal cord stimulator and careful patient selection, we have a lot of success with patient who is suffering from post laminectomy pain syndrome, complex reginal pain syndrome and diabetic neuropathy. Based on our data collection, we have about 84% success rate using spinal cord stimulator. Spinal cord stimulator is not a modalities for everyone, but it should be offered to patients with the right diagnosis and the right psychosocial support and wellbeing.

We are privileged to be Washingtonian and should not be denied the same benefit compare to Medicare, other private insurance carriers or other state insurance. We like to offer an effective treatment to all our patients.

We asked the committee to review the scientific data and reconsider for the coverage of spinal cord stimulator based on new clinical studies and physicians feedback.

Thank you,

Neil Batta, MD

Neil Batta, MD
Neospine
[redacted]

Hamann, Valerie (HCA)

From: Adam Burkey [redacted]
Sent: Thursday, September 8, 2022 6:44 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation Re-review

External Email

I am an interventional pain physician so I understand that any comments in favor of this therapy may seem self-serving. However, if one has been in the field for nearly twenty years as I have, one can see that the increased utilization of these devices is due to the ever increasing effectiveness of the therapy. Costs and risks should be judged relative to the alternatives for patients, whether that is repeat spinal surgery for those patients with intractable back and leg pain after fusion or laminectomy, or a lifetime of medication, wound care and possible amputation for those with diabetes and small-vessel disease in their lower extremities.

Cost-effectiveness and the incidence of complications from SCS implant are documented in the literature elsewhere, as well as reductions in opioid usage and other benefits. These complications are very rarely serious or life-threatening and usually entail a simple revision procedure. I also won't rehearse the decades of data, well-known even a decade ago (https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004001.pub3/full) on its utility for vascular disease. Indeed, SCS is used more in Europe for chronic angina and peripheral vascular disease, where it improves perfusion, treats pain and reduces amputation, than it is for failed back surgery syndrome. To claim that this therapy, which has existed for many years and used by many thousands of physicians and benefiting many hundreds of thousands of patients world-wide, is placebo is nonsensical to me. To insinuate the whole industry relies on placebo and is driven by greed, a decades-long fraud of immense magnitude, is simply impossible and untrue.

It is true that prior to 2015, with the devices available at that time, all of which produced sensory tingling and paresthesia with low energy, did not work nearly as well as today's devices. At that time it was difficult to capture back pain; it was most successful for neuropathic pain in a limb or vascular/ischemic pain. It is also borne out in studies that patients in litigation or pursuing disability/worker's compensation claims have much reduced response to the therapy, which is easily explained by their financial secondary gain motives.

Since 2015 a bevy of new approaches have been developed which do not produce any discernible sensation to the patient; they could not tell if it were on or off except that their pain is reduced. But these devices, in study after study compared to the older techniques which produce a sensation, outperform the older models. This argues against placebo, which is usually cued and reinforced by sensory stimuli.

Finally, since I do not know if this work was cited in the re-review petition, there are studies of an even newer technology, not yet available in the States, which continuously adjusts its output based on electrical parameters measured in the epidural space (see references below). This device was compared to itself with regard to effectiveness, and the "closed-loop" technology was found superior to the "open-loop" system where it did not adjust its output. So you again have a study with two active arms and the patient blinded to which therapy they are receiving, and yet superiority of one over the other is demonstrated. This cannot be placebo.

I certainly hope the citizens of Washington currently being denied this therapy will have it made available to them. They are being left behind and in the lurch, oddly since this region is known for its forward-thinking with regard to advanced technology and its adoption.

AB

Mekhail N, Levy RM, Deer TR, et al. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomized, controlled trial. Lancet Neurol. 2020;19(2):123-134.

Mekhail N, Levy RM, Deer TR, et al. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain; A Secondary Analysis of the Evoke Randomized Clinical Trial. JAMA Neurol. 2022;79(3):1-10.

Adam R. Burkey, MD, MSCE, FAAN
Medical Director

ANESIS
SPINE & PAIN CARE

Hamann, Valerie (HCA)

From: Z F [redacted]
Sent: Thursday, August 25, 2022 3:21 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS technology commentary

External Email

To whom it may concern,

Pain clinics such as ours use neuromodulation including spinal cord stimulation in patients who have exhausted most other avenues of treatment for their chronic, debilitating pain. The treatment is minimally invasive with very rare complications or side effects. Patients typically receive psychological screening to ensure they have the mental state to manage an implant. This modality of treatment has been around for decades and there are national conferences each year (NANS https://neuromodulation.org/Default.aspx for example) dedicated to this field. It is a travesty that we cannot utilize this modality for patients who are referred to us desperate for relief. These patients are left with few alternatives by the time they consider SCS or similar neuromodulatory modality. Generally their only remaining options at this point are chronic pain and suffering, high dose opioid addiction, invasive surgeries that are unlikely to be effective and carry a high risk of complication, and contemplation of suicide in a significant minority of cases. Please allow us to use this treatment option rather than hamstringing us and hurting our patients. Every other insurance company we work with allows us to use spinal cord stimulation including CMS. It is policies like these that force most pain clinics to reject labor and industry cases.

Sincerely
Zach Fisk, MD, MBA
CEO, Acute Pain Therapies
Member of the Sound Pain Alliance
Vice President of the Washington Academy of Pain Management

Hamann, Valerie (HCA)

From: Jon Geffen [redacted]
Sent: Thursday, September 8, 2022 8:37 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal cord stimulation

External Email

Hello,
I am writing in favor of allowing payment for spinal cord stimulation. I'm a pain physician and have been using this technology for 10 years. There are so many Washington state patients that would benefit from this treatment.
Kind regards,
Jon Geffen, DO

Hamann, Valerie (HCA)

From: Jon Geffen [redacted]
Sent: Friday, September 9, 2022 11:06 AM
To: HCA ST Health Tech Assessment Prog
Subject: I support spinal cord stimulation for all patients in Washington state

External Email

I've practiced pain management in Washington state since 2005. There are a few more comments I'd like to share in support of having spinal cord stimulation for all patients in Washington state:

1. WA is the only State that does not cover SCS
2. Several large, Level 1 Randomized controlled trials have been published in peer reviewed journals in recent years (feel free to reference Senza RCT, Senza PDN, Senza Non-Surgical Refractory Back)
3. Given who typically is covered through a WA HCA administered health plan, the lack of access to SCS is creating health inequities within marginalized and socio-economically disadvantaged groups. Also, our valued state employees such as teachers are left to suffer when all other interventions fail.

Thanks, Jon Geffen, DO

Hamann, Valerie (HCA)

From: christopher godbout [redacted]
Sent: Friday, September 9, 2022 7:18 PM
To: HCA ST Health Tech Assessment Prog
Cc: christopher godbout
Subject: Spinal cord stimulator

External Email

Dear committee members:

I am encouraged the committee has agreed to review coverage for spinal cord stimulation.

I'm certain the committee is aware neuromodulation therapy delivered to the spinal cord by an implanted device is FDA approved for spine and limb pain mostly common with failed back syndrome and complex regional pain syndrome(CRPS). In fact, the FDA has recently approved the therapy for painful diabetic neuropathy and non-surgical recalcitrant low back pain.

Recent randomized controlled trials have proven the efficacy and patient tolerability, along with exceptionally low risk of side effects and minimal risk of harm.

Neuromodulation therapy and spinal cord stimulation allows cost reduction and reduced medical interventions and imaging. Moreover, spinal cord stimulation therapy offers an improvement in functional daily activity and quality of life - the primary desired outcome.

Since practicing in Washington State I have seen the inequities and lack of access to medically necessary treatments (spinal cord stimulation), based solely on socio-economic status of patients covered through WA HCA administrated health plans.

As an interventional pain management physician, I have used spinal cord stimulation with amazing success (86-93%) which exceeds outcomes from spinal surgery and other interventional therapies.

Many patients in my office are great candidates and meet medical necessity for spinal cord stimulation but can not receive this valuable life changing therapy because they receive subsidized Medicaid
managed by WA HCA.

Patients have few options when spinal cord stimulation is not allowed. They have already failed all conservative therapies and interventional treatments (ESI, RFA, joint injections, acupuncture, ect.), surgery, and find multiple medications used in combination ineffective or intolerable.

Citizens of Washington State should be offered best care, including the gold standard for persistence spine and/or leg pain: spinal cord stimulation.

The federal government and 49/50 states cover SCS. Only Washington does not cover. All commercial health plans cover SCS.

Thank you for reconsideration.

Best,

Christopher Godbout, MD
Interventional Pain Management
Multicare Health Systems

Hamann, Valerie (HCA)

From: David Hou [redacted]
Sent: Wednesday, September 7, 2022 9:08 PM
To: HCA ST Health Tech Assessment Prog
Cc: david Hou
Subject: Spinal cord stimulator

External Email

To whom it may concern:

I am writing to you regarding spinal cord stimulator.

As a pain physician, I have used this effective device to treat refractory pain patients for more than 16 years.

I personally see a lot of my patients benefit from this device.

It is so sad that Washington State insurance does not cover this effective treatment.

I ask the committee to review the scientific data and reconsider this effective treatment for our Washington citizens.

Thank you so much for your reconsideration.

David Hou, MD

Hamann, Valerie (HCA)

From: Koogler, Andrew [redacted]
Sent: Monday, September 12, 2022 7:51 AM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal cord stimulator review

External Email

To whom it may concern:

I am writing to you regarding the spinal cord stimulation review for Washington state.

I am a pain management physician in Washington who performs such procedures. Washington is the only state that does not cover spinal cord stimulation for patients which is very sad for patients residing in this state. Having a mother who is a former teacher, I find it heartbreaking that if she was suffering from a chronic pain condition that could benefit from this type of therapy, she would be denied coverage for treatment. I am thankful she taught and lives in a different state that has better coverage for their state employees.

I ask the committee to review the scientific data and reconsider this effective treatment for our Washington citizens.

Thank you so much for your reconsideration.

Regards,
Andrew Koogler, MD

--

Andrew Koogler, MD
Puget Sound Pain Clinic
[redacted]
www.wapaindoctor.com

Hamann, Valerie (HCA)

From: Jeffrey McLaren [redacted]
Sent: Monday, September 12, 2022 2:47 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord stimulator HCA review

External Email

Dear Mrs. Birch and fellow HCA members

Thank you for your consideration of spinal cord stimulator therapy for Washington state. As I'm sure you have heard already this therapy can be life altering for some of our residents. I can say that I share your concerns about it's utilization within the state but I agree with many of my colleagues that this care should be available to our patients. I hope if this therapy is approved that there is also a plan for review and authorization that ensures abuse of this therapy does not happen. I encourage you to hold the companies making these products accountable to help Washington State build tools to ensure that our patients continue to see benefit from this therapy and those of us implanting them can be held to a similar high standard of selection. I would be happy and excited to work on such an endeavor. Thank you for your time and consideration.

Sincerely,
Jeff McLaren MD
Anesthesia and Interventional Pain Medicine
Kaiser Permanente Washington
Board Member
Washington State Society of Anesthesiologists

Hamann, Valerie (HCA)

From: Nishio, Isuta (Puget Sound) [redacted]
Sent: Sunday, September 11, 2022 10:17 PM
To: HCA ST Health Tech Assessment Prog
Subject: WA Health Care Authority HTA Topic for SCS

External Email

Ms. Susan Birch,

As a pain specialist and anesthesiologist taking care of chronic pain patients for 25+ years, I know Spinal cord stimulation (SCS) may help a group of selected patients eg .neuropathic pain in extremities. However, I am concerned about strong push to expand indications and coverage of this tx to other chronic pain conditions such as chronic axial (non-specific) low back pain. Over the last 10+ years, I have reviewed quite a few cases in Alaska VA, requests for SCS by a local pain specialists. I found most of them were not good candidates. I have seen many patients who have SCS implanted, but not helping or using it. Even "successful SCS" does not lead to reduction of other pain treatment or opioid medications. It is well known that it has relatively high rate of complications, most of which are device/leads related though. It has been shown that multidisciplinary pain rehabilitation program is 25 times more cost effective.

Thank you,

Isuta Nishio MD, PhD

Associate Professor
Department of Anesthesiology and Pain Medicine

VA Puget Sound Health Care System
Seattle WA

Hamann, Valerie (HCA)

From: David Velling [redacted]
Sent: Monday, September 5, 2022 2:43 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS Re-review by HTA Program

External Email

To the Members of the HTA Program / HTCC,

Spinal Cord Stimulation (SCS) has been selected for re-review by the HTA / HTCC, having been initially reviewed in 2010 and (unfortunately) rejected for coverage by the state of Washington.
There is currently significant and sufficient medical literature to support a decision by the HTA / HTCC to cover SCS as a treatment option for patients with the following disorders: non-surgical chronic low back pain, chronic lumbar radiculopathy/radiculitis, lumbar post-laminectomy syndrome and complex regional pain syndrome(CRPS). This should include coverage for ALL Washington state residents insured through the state of Washington, which includes employees of the state as well as injured workers (through L & I).
Currently WA state is the ONLY state in the U.S. which denies this coverage to its injured workers and employees. All other state, federal and private worker's compensation insurance carriers provide this coverage. All commercial insurance carriers and Medicare provide this coverage to employees and residents of the US. This is shocking, and truly a disservice to the residents of the state of WA.
I have practiced medicine in the state of WA since 2002, providing pain management services to thousands of WA residents, many whom have been insured by the state of WA and been denied coverage for this procedure which could have helped them. They have been forced to suffer unnecessarily, all due to a poor decision made by the HTA / HTCC in 2010 based upon a biased and inadequate review of the existing literature at the time. I have advised patients to change insurance from a WA state sponsored policy to other coverage in order to be able to have the care they need. This is a life-changing treatment for people with chronic pain that is unresponsive to other treatment options. It helps prevent unnecessary suffering.
I hope that a thorough and unbiased literature review by the HTA / HTCC at this time will result in a more balanced and well-informed view, and that SCS will be authorized for use in those patients and injured workers deserving of this well-established standard medical treatment option.

Respectfully,

David Velling MD
Medical Director
Genesis Spine, Joint and Regenerative Medicine
[redacted]

Board Certifications:
American Board of Anesthesiology (ABA)
American Board of Anesthesiology-Pain Management
American Board of Pain Medicine (ABPM)

Hamann, Valerie (HCA)

From: Hockenson, Kevin [redacted]
Sent: Monday, September 12, 2022 4:08 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS for patients
Attachments: SCS petition Wang.pdf

External Email

To Whom It May Concern,

We are writing to you to take serious consideration to cover Spinal Cord Stimulator therapies for the 2.5 million Washingtonians.

As a multispecialty spine practice that offers patients conservative therapies, injection and surgery. We have provided care for our community for many decades. With the advancement of spinal cord stimulator and careful patient selection, we have a lot of success with patient who are suffering from post laminectomy pain syndrome, complex reginal pain syndrome and diabetic neuropathy. Based on our data collection, we have about 84% success rate using spinal cord stimulator. Spinal cord stimulator is not a modalities for everyone, but it should be offered to patients with the right diagnosis and the right psychosocial support and wellbeing.
We are privileged to be Washingtonian and should not be denied the same benefit compared to Medicare, other private insurance carriers or other state insurance. We would like to offer an effective treatment to all our patients.

We asked the committee to review the scientific data and reconsider the coverage of spinal cord stimulator based on new clinical studies and physician's feedback.

Thank you,
Kathy Wang, DO
Kathy Wang, DO
Neospine
[redacted]

To Whom It May Concern,

We are writing to you to take serious consideration to cover Spinal Cord Stimulator therapies for the 2.5 million Washingtonians.

As a multispecialty spine practice that offer patients conservative therapies, injection and surgery. We have provided care for our community for many decades. With the advancement of spinal cord stimulator and careful patient selection, we have a lot of success with patient who is suffering from post laminectomy pain syndrome, complex reginal pain syndrome and diabetic neuropathy. Based on our data collection, we have about 84% success rate using spinal cord stimulator. Spinal cord stimulator is not a modalities for everyone, but it should be offered to patients with the right diagnosis and the right psychosocial support and wellbeing.

We are privileged to be Washingtonian and should not be denied the same benefit compare to Medicare, other private insurance carriers or other state insurance. We like to offer an effective treatment to all our patients.

We asked the committee to review the scientific data and reconsider for the coverage of spinal cord stimulator based on new clinical studies and physicians feedback.

Thank you,

Kathy Wang, DO

Kathy Wang, DO
Neospine
[redacted]

Hamann, Valerie (HCA)

From: ross vogelgesang [redacted]
Sent: Friday, September 9, 2022 11:46 AM
To: HCA ST Health Tech Assessment Prog
Subject: Review of Spinal Cord Stimulator Efficacy.

External Email

Dear Committee Members,

Thank you for the time and effort you spend assess and deciding on best medical care allowances for the persons of Washington state their healthcare beneficiaries.

As you know, medicine is an ever-changing industry and necessitates frequent readjusting of practices to keep up with this changing environment. If I continued to practice medicine the way I was trained I would have had my licensed revoked long ago. You are now at a junction where previous decisions by committee members may no longer support the decision not to cover spinal cord stimulation.

I was on the sidelines of spinal cord stimulation in years past. I am now an avid supporter of them. The science behind a particular system that I use most often in my practice has been similar to the published peer reviewed studies available for your review. (Reference: SENZA-RCT2, Clinical Data presented at NANS 2021 reported a >65% reduction in opioid use, Joirnal of Pain, 2018 reporting Novel HFX response to pain reduction, Journal of Anesthesiology 2015 reporting novel therapy with far superior outcomes to pain reduction, and there are many more supporting publications).

I know life is busy, often staying the course is far easier than making changes. I hope you recognize that this is a time that change is finally due. I support the acceptance of adding spinal cord stimulation to allowable medical practice. I hope you can support the same with enthusiasm.

Best regards,
Ross Vogelgesang, MD
Class of 1988
Sent from my iPhone

Hamann, Valerie (HCA)

From: Daniel Kwon [redacted]
Sent: Monday, August 22, 2022 2:20 PM
To: HCA ST Health Tech Assessment Prog
Subject: spinal cord stimulation

External Email

I represent a group of physicians at Yakima Valley Memorial Hospital in Yakima, WA.
I am a pain physician/specialist and have been working with chronic pain patients for many years in WA state.
I believe that spinal cord stimulators can be a valuable tool in the right patient.

There is a significant amount of new published data in multiple peer reviewed journals. One simple example is the use of high frequency spinal cord stimulators (Nevro corp.) that has been FDA approved years after the initial HTA review.

I request that the HTA re-review spinal cord stimulators in light of new technology, new publications, and re-consider how we can help our patients that live and work in Washington state.

Sincerely,

Daniel Kwon, MD
Physician Lead
Yakima Valley Memorial Hospital

Hamann, Valerie (HCA)

From: Mcguire, Teddi A [redacted]
Sent: Monday, September 12, 2022 4:12 PM
To: HCA ST Health Tech Assessment Prog
Subject: Health Technology Assessment - spinal cord stimulation rereview
Attachments: Providence comment Letter - Spinal cord stimulation.pdf

External Email

Good afternoon,

Please see attached letter from Providence as part of the public comment for the rereview.

Please let me know if you have any questions.

Best,
Teddi

Teddi McGuire
Program Manager, Government Affairs, WA & MT
Providence | Swedish Health Services | Kadlec Regional Medical Center | Pacific Medical Centers

[redacted]

Hamann, Valerie (HCA)

From: Emilie Jones
Sent: Monday, August 15, 2022 8:56 AM
To: HCA ST Health Tech Assessment Prog
Subject: SCS review

External Email

Hello,
I wanted to write as an individual (not representing the UW) expressing my support for expanding coverage for spinal cord stimulation through the HCA. There are rigorous inclusion criteria in place to ensure appropriate and judicious use of SCS. Additionally I have seen many patients with disabling peripheral neuropathy, many of whom could have a significant improvement in their ability to work and lead meaningful lives with proper pain control. I hope the HTAP reviews current evidence and supports inclusion of SCS for chronic pain and peripheral neuropathy.
Thank you,
Emilie

Emilie Jones, PT, DPT

Service Line Administrator
Spine Program | **UW Medicine**

WEB: uwmedicine.org

Pronouns | She, Her

Hamann, Valerie (HCA)

From: David T. Pitkethly [redacted]
Sent: Monday, August 29, 2022 10:38 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation

External Email

My name is David Pitkethly and I am a 86 year old retired neurosurgeon. I first experienced low back pain as a college student. By age 40 the pain was severe and I had my first fusion of my fifth lumbar vertebra to sacrum for spondylolisthesis. Four operations later, including two more fusions, my low back pain is with me most of the time.

Two weeks ago I underwent placement of two temporary spinal epidural leads with electrodes by Dr. Brett Stacy, Professor and Medical Director at the Center for Pain Relief at the University of Washington. This was a trial to see if a spinal cord stimulator, SCS, would relieve any of my low back pain. I found that about 70% of my pain was relieved, and I was able to stop all pain medications during the trial. Now I am awaiting placement of a permanent spinal cord stimulator system.

I am fortunate in that I have an excellent medical insurance plan which will pay for almost all of my expenses.

I understand that there are many citizens of Washington State with disabling spine/lower extremity pain, that have medical insurance plans paid all or in part by the State of Washington, and that these individuals are denied coverage for spinal cord stimulation (SCS).

SCS is a very valuable treatment option for patients with debilitating spine/lower extremity pain. When effective, these individuals can reduce or discontinue pain medications, return to normal activities of daily living, and return to the work force.

I appeal to HTA to recommend that this valuable and proven effective treatment, SCS, be a covered treatment for Washington State citizens who have Washington State health insurance programs.

Thank you very much,
David Pitkethly MD

David T. Pitkethly, MD, FACS
Professor Emeritus
University of Washington
Department of Neurological Surgery
[redacted]

Hamann, Valerie (HCA)

From: brett stacey [redacted]
Sent: Sunday, September 11, 2022 10:35 PM
To: HCA ST Health Tech Assessment Prog
Cc: brett stacey; Brett R. Stacey
Subject: SCS HTA
Attachments: HTA Comment BRS 9.2022.docx

External Email

Dear HTCC:

I am an academic Pain Medicine physician who cares for many patients covered by HCA-connected health insurance.

I am writing to urge spinal cord stimulation (SCS) health insurance coverage be extended to those 2.5 million Washingtonians with HCA-connected health insurance. It has been 12 years since the topic was last reviewed. Much has changed with SCS that should lead to a favorable decision from your group. I know you will have a full literature review prepared for you, but I wish to highlight important advancements in the last dozen years.

First, since 2015 the FDA-approved technology has changed with new mechanisms of action demonstrating superiority to prior SCS paradigms in multiple randomized controlled trials.(1-5) The studies with these newer technologies are larger and more robust than studies reviewed in 2010.

These improvements mean many patients typically experience 70-80% pain reduction. No other treatments have pain relief of this magnitude. The improvements in the technology mean that newer systems are largely MRI compatible with longer battery life and improved durability.

Second, there is a new FDA approved indication—painful diabetic peripheral neuropathy (DPN) with impressive reductions in pain accompanied by improvements in function and neurologic status.(6-11) It is estimated that 700,000 Washingtonians have diabetes, and it is estimated that 15-25% of diabetic patients have painful DPN. Painful DPN disproportionately impacts patients with poor health literacy, those with fewer economic resources, and racially disadvantaged groups in the United States. These groups have less access to advanced diabetes care such as insulin pumps and have worse outcomes in many areas for diabetes treatment.(12-17) Lack of coverage for HCA—covered patients with painful DPN sets up health care disparities and inequities that are not justifiable.

Third, recent studies have demonstrated cost-effectiveness of SCS, including improvement in employment status.(11, 18-25) Because of the data demonstrating clinical efficacy and cost-effectiveness, SCS is covered in every other state in the United States, throughout Europe, and in the UK. Spinal cord stimulation is covered by most Washington State insurers including Medicare. The Washington HCA is out of step with the rest of modern medical care for difficult to treat chronic pain patients.

Fourth, SCS can provide an alternative to opioids and result in opioid reduction. (26-29) As the opioid crisis persists in our state, we need every effective tool available.

Finally, for patients with persistent pain following spinal surgery, complex regional pain syndrome, or painful diabetic peripheral neuropathy that has not responded to typical first line treatment options there is no widely applicable and available alternative with the potential for such life altering pain improvement.

For all of these reasons, I ask that you expand SCS coverage to Washingtonians with insurance covered by the HCA.

Brett R. Stacey

1. Kallewaard JW, Gültuna I, Hoffmann V, Elzinga L, Munnikes R, Verbrugge L, et al. 10 kHz Spinal Cord Stimulation for the Treatment of Failed Back Surgery Syndrome with Predominant Leg Pain: Results from a Prospective Study in Patients from the Dutch Healthcare System. Pain practice : the official journal of World Institute of Pain. 2021;21(5):490-500.
2. Al-Kaisy A, Van Buyten JP, Kapural L, Amirdelfan K, Gliner B, Caraway D, et al. 10 kHz spinal cord stimulation for the treatment of non-surgical refractory back pain: subanalysis of pooled data from two prospective studies. Anaesthesia. 2020;75(6):775-84.
3. Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. Pain Med. 2014;15(3):347-54.
4. Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery. 2016;79(5):667-77.
5. Hagedorn JM, Falowski SM, Blomme B, Capobianco RA, Yue JJ. Burst spinal cord stimulation can attenuate pain and its affective components in chronic pain patients with high psychological distress: results from the prospective, international TRIUMPH study. Spine J. 2022;22(3):379-88.
6. Strand NH, Burkey AR. Neuromodulation in the Treatment of Painful Diabetic Neuropathy: A Review of Evidence for Spinal Cord Stimulation. J Diabetes Sci Technol. 2022;16(2):332-40.
7. Petersen EA, Stauss TG, Scowcroft JA, Brooks ES, White JL, Sills SM, et al. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. Diabetes Care. 2022;45(1):e3-e6.
8. Petersen EA, Stauss TG, Scowcroft JA, Brooks ES, White JL, Sills SM, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA neurology. 2021;78(6):687-98.
9. Duarte RV, Nevitt S, Maden M, Meier K, Taylor RS, Eldabe S, et al. Spinal cord stimulation for the management of painful diabetic neuropathy: a systematic review and meta-analysis of individual patient and aggregate data. Pain. 2021;162(11):2635-43.
10. Galan V, Scowcroft J, Chang P, Li S, Staats P, Rotte A, et al. 10-kHz spinal cord stimulation treatment for painful diabetic neuropathy: results from post-hoc analysis of the SENZA-PPN study. Pain management. 2020;10(5):291-300.
11. Slangen R, Faber CG, Schaper NC, Joosten EA, van Dongen RT, Kessels AG, et al. A Trial-Based Economic Evaluation Comparing Spinal Cord Stimulation With Best Medical Treatment in Painful Diabetic Peripheral Neuropathy. J Pain. 2017;18(4):405-14.
12. Phonyiam R, Berry DC. Racial and Ethnic Disparities in Health Care and Health Outcomes for Pregnant Women With Diabetes. Nurs Womens Health. 2021;25(6):437-49.
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Hamann, Valerie (HCA)

From: brett stacey [redacted]
Sent: Sunday, September 11, 2022 10:35 PM
To: HCA ST Health Tech Assessment Prog
Cc: brett stacey; Brett R. Stacey
Subject: SCS HTA
Attachments: HTA Comment BRS 9.2022.docx

External Email

Dear HTCC:

I am an academic Pain Medicine physician who cares for many patients covered by HCA-connected health insurance.

I am writing to urge spinal cord stimulation (SCS) health insurance coverage be extended to those 2.5 million Washingtonians with HCA-connected health insurance. It has been 12 years since the topic was last reviewed. Much has changed with SCS that should lead to a favorable decision from your group. I know you will have a full literature review prepared for you, but I wish to highlight important advancements in the last dozen years.

First, since 2015 the FDA-approved technology has changed with new mechanisms of action demonstrating superiority to prior SCS paradigms in multiple randomized controlled trials.(1-5) The studies with these newer technologies are larger and more robust than studies reviewed in 2010.

These improvements mean many patients typically experience 70-80% pain reduction. No other treatments have pain relief of this magnitude. The improvements in the technology mean that newer systems are largely MRI compatible with longer battery life and improved durability.

Second, there is a new FDA approved indication—painful diabetic peripheral neuropathy (DPN) with impressive reductions in pain accompanied by improvements in function and neurologic status.(6-11) It is estimated that 700,000 Washingtonians have diabetes, and it is estimated that 15-25% of diabetic patients have painful DPN. Painful DPN disproportionately impacts patients with poor health literacy, those with fewer economic resources, and racially disadvantaged groups in the United States. These groups have less access to advanced diabetes care such as insulin pumps and have worse outcomes in many areas for diabetes treatment.(12-17) Lack of coverage for HCA—covered patients with painful DPN sets up health care disparities and inequities that are not justifiable.

Third, recent studies have demonstrated cost-effectiveness of SCS, including improvement in employment status.(11, 18-25) Because of the data demonstrating clinical efficacy and cost-effectiveness, SCS is covered in every other state in the United States, throughout Europe, and in the UK. Spinal cord stimulation is covered by most Washington State insurers including Medicare. The Washington HCA is out of step with the rest of modern medical care for difficult to treat chronic pain patients.

Fourth, SCS can provide an alternative to opioids and result in opioid reduction. (26-29) As the opioid crisis persists in our state, we need every effective tool available.

Finally, for patients with persistent pain following spinal surgery, complex regional pain syndrome, or painful diabetic peripheral neuropathy that has not responded to typical first line treatment options there is no widely applicable and available alternative with the potential for such life altering pain improvement.

For all of these reasons, I ask that you expand SCS coverage to Washingtonians with insurance covered by the HCA.

Brett R. Stacey

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Hamann, Valerie (HCA)

From: Sandeep Patil [redacted]
Sent: Monday, September 12, 2022 3:26 PM
To: HCA ST Health Tech Assessment Prog
Subject: Health Technology Assessment - Spinal Cord Stimulation Re-Review
Attachments: WA HTA Nevro Comment Letter_9.12.22.pdf; Senza Product Dossier.pdf; ECRI_ClinicalEvidence_Senza Spinal Cord Stimulation System for Treating Chronic Pain_May2022_Payer Version.pdf; Clinical Evidence.zip

External Email

Dear Washington Health Care Authority,

We have attached a formal comment letter and associated documentation to facilitate the re-review process for Spinal Cord Stimulation. Attached you will find the following documents:

- Nevro Comment Letter
- Senza Product Dossier
- ECRI Clinical Evidence Assessment for Senza Spinal Cord Stimulator
- Published Peer Reviewed Evidence from 10 kHz SCS RCTs and Additional Publications (zipped file)

If you have any questions about the attached, please don't hesitate to reach out. Thank you for your consideration.

Sandeep Patil
Director, Reimbursement and Healthcare Access
[redacted]

Senza® Spinal Cord Stimulation (SCS) System

SENZA Spinal Cord Stimulation Dossier

Addressing Effective Pain Management for
Painful Diabetic Neuropathy (PDN) &
Chronic Intractable Pain of the Trunk &/or Limbs including
Non-Surgical Refractory Back Pain (NSRBP)

Prepared by:
Nevro Corp.
April 2022

Executive Summary

Nevro's Senza® Spinal Cord Stimulation ("SCS") System ("Senza SCS") (includes Senza®, Senza II™, and Senza Omnia™) has treated over 80,000 patients since 2015 for the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. The Senza SCS system has proven safety and effectiveness data for the management of chronic intractable pain of the trunk and/or limbs. The vast majority of commercial payers currently cover the use of Senza SCS for the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain.

The Senza SCS provides a novel therapy that utilizes 10 kHz High-Frequency SCS, a unique mechanism of action that is paresthesia-independent and has demonstrated significant pain relief for chronic back and leg pain compared to traditional 40 – 60 Hz SCS treatment. This results in no driving restrictions or impact on sleep that enables average daily use of 24 hours vs 17 hours with traditional SCS.

In July 2021, Nevro's PMA supplement for the Senza SCS was approved by FDA for expanded use in treating painful diabetic neuropathy (PDN) when programmed to include a frequency of 10 kHz and aids in the management of chronic intractable pain of lower limbs, including unilateral or bilateral pain, associated with PDN. The Senza System is the first and only 10 kHz FDA approved SCS treatment for PDN.

PDN is associated with high clinical utility, considerable direct and indirect economic costs and treatment-discontinuation rates (Kiyani 2020; O'Connor 2009; Pop-Busui 2017; Sadosky 2015; Yang 2015). A retrospective analysis, using the Humedica Electronic Medical Record (EMR) claims database, was conducted to evaluate the healthcare costs in patients with diabetes (n=288,328) relative to clinical PDN. The authors observed a trend toward increased clinical utility from diabetes-only patients, as well as patients who reported pain (PDN) due to diabetic peripheral neuropathy.

Direct medical costs were 4x higher for patients with PDN vs patients with diabetes alone (Sadosky 2015). Severe pain in PDN patients was associated with increased costs and higher clinical utility. When compared to the PDN cohort, patients with severe PDN had higher rates of emergency department visits and hospitalizations respectively (Sadosky 2015). A retrospective claims analysis using the MarketScan database found that baseline costs associated with PDN patients were 20% higher than patients with diabetes alone (Kiyani 2020).

In addition to the FDA approval for PDN, Nevro received FDA approval through PMA Supplement in January 2022 to treat non-surgical refractory back pain (NSRBP). This approval is specific to Nevro's proprietary 10 kHz SCS therapy and differentiates Nevro's system as the only SCS system with specific labeling to treat NSRBP patients. Non-surgical refractory back pain is defined as patients who have not had a prior spine surgery and are not deemed to be a surgical candidate based on an evaluation with a surgeon.

Centers for Medicare and Medicaid Service (CMS) has a published National Coverage Determination (NCD) 160.7 on Electrical Nerve Stimulators which covers implantable dorsal column stimulators (also known as spinal cord stimulators) as a late or last resort for patients with chronic intractable pain who have tried other treatment modalities but did not achieve satisfactory relief or were judged to be unsuitable or contraindicated for them. This broad coverage policy includes multiple chronic pain indications, including PDN and NSRBP. The original base indications are well-covered by national and regional commercial health plans as well.

While several treatment options exist for PDN they are not successful for all patients, and those with unsuccessful treatments continue to experience intractable pain, which leads to expensive resource consumption. Approximately 11% of the total diabetic population experience refractory PDN, which is the target group for the Senza SCS.

Nevro developed the next-generation approach to SCS utilizing High-Frequency 10 kHz (HF10™/HFX™) stimulation that provides PDN patients with significant pain relief and no paresthesia. The Senza SCS implements a trial phase lasting 3-14 days to confirm effectiveness (defined as 50% pain relief from baseline) prior to moving the patient to the implant phase. In a recent publication (Petersen, 2021) from the SENZA-PDN, 86% (75/87) of patients reported ≥50% pain relief with no worsening in neurological deficit at 3 months compared with 5% (5/94) of patients in the conservative medical management cohort. The study also identified that over 90% of patients moved from the trial phase to the implant phase. Additionally, in a publication of long-term durability of pain relief (Petersen, 2021) from the SENZA-PDN RCT, at 12 months, 86% of participants in the 10 kHz SCS study arm reported at least >50% pain relief, while the average pain relief was 77.1% (% reduction of VAS from baseline).

All of the Nevro Senza SCS devices within the portfolio utilize a rechargeable implantable pulse generator (IPG). The Senza system received CE mark in 2010, TGA approval in 2011, FDA PMA approval in 2015, and is commercially available in Europe, Australia, and the United States. In the U.S., Nevro's SCS systems are approved to deliver both traditional SCS low frequencies of 2 –1,200 Hz and are the only systems approved to deliver 10 kHz frequencies.

SAMPLE PAYER POLICY (Key Components Within Actual Policy)

MEDICAL NECESSITY:

Prior authorization is required for spinal cord stimulation trial and permanent implantation, including reoperation.

I. Indications for TRIAL spinal cord stimulation:

Documentation in the *PAYER* medical policy indicates that all of the following criteria have been met:

A. Device has PMA FDA Approval to treat the following indications:
   1. Patients with failed back surgery syndrome (FBSS) with intractable neuropathic leg pain when the following criteria are met
      a) Patient has failed at least six consecutive months of physician-supervised, conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
      b) Surgical intervention is not indicated, or patient does not wish to proceed with spinal surgery
   2. Patients with complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) only of the upper and lower extremities, when the following criteria are met
      a) Patient's diagnosis is CRPS/RSD
      b) Patient has failed at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification).
   3. Patients with chronic, intractable pain secondary to chronic critical limb ischemia (CLI), when the following criteria are met
      a) Attestation is received from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction.
      b) Patient has a diagnosis of CLI with Rutherford Classification (see Description section below) Grade II, Category 4 ischemic limb rest pain that is characterized by BOTH of the following: a. resting ankle pressure less than 40 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; and b. toe pressure less than 30 mmHg.
      c) Advanced imaging (i.e., angiographic imaging, computed tomography (CT) scan or magnetic resonance imaging (MRI)) demonstrates multi-level disease with absence of named vessel with flow into the foot.
   4. Patients with moderate to severe diabetic peripheral neuropathy (VAS ≥ 5) when the following criteria are met
      a) Pain refractory to a minimum of six months of conservative therapy, including at least two of the following therapies:
         1) Non-steroidal anti-inflammatory drug [NSAIDs]
         2) Antidepressant
         3) Anticonvulsant
         4) Opioids
      b) Patient has been assessed to be a safe surgical candidate based on perioperative care guidelines established in the American Diabetes Associations' Standards in Medical Care in Diabetes and/or guidance from the Society for Ambulatory Anesthesia.
   5. Patients with chronic intractable back pain who are not surgical candidates and have not had a prior spine surgery when the following are met

a) Patient has failed at least six consecutive months of physician-supervised, conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
b) Surgical intervention is not indicated, or patient does not wish to proceed with spinal surgery

B. Documentation of all of the following:
   1. Intractable pain for a minimum of six months duration
   2. Failure of standard therapy or unsuitability of standard therapies
   3. Comprehensive physical examination, including a pain evaluation

C. Psychological evaluation has been conducted, and all of the following apply:
   1. Evaluation has been completed within the past 12 months
   2. Continued optimal management of any previously diagnosed (greater than 12 months) mental or neurobehavioral condition(s).
   3. No evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement

II. Indications for PERMANENT spinal cord implantation:

Documentation in the *PAYER* records indicates that all of the following criteria have been met:

A. *PAYER* necessity criteria is consistent with I.A.- D. above.

B. Individual has completed a trial using either percutaneous leads or surgically implanted leads with documentation of all of the following:
   1. Trial duration of a minimum of 48 hours
   2. Greater than or equal to 50% reduction in pain using a standard pain relief inventory assessment tool (e.g., Visual Analog Scale, Numeric Rating Scale, Verbal Rating Scale).

III. Indications for reoperation:

Documentation in the *PAYER* record indicates one of the following:

A. Development of fibrosis surrounding the electrode tip
B. Electrode misalignment or migration has occurred
C. Infection necessitating removal of the stimulation system
D. Spinal cord stimulator and/or the battery are no longer operational

Preface

Nevro's Senza SCS is FDA approved as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. The Senza SCS has proven safety and effectiveness data for the aid in the management of chronic intractable pain of the trunk and/or limbs.

Senza SCS was recently approved by FDA for expanded use for PDN (July 2021) and Non-Surgical Refractory Back Pain (January 2022). The FDA's approval language for both indications is below.

PDN

"The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy."

Non-Surgical Refractory Back Pain (NSRBP)

"The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery)."

The safety and effectiveness of Senza SCS for aid in the management of non-surgical refractory back pain and painful diabetic neuropathy (PDN) in patients with symptoms refractory to conservative treatment is currently being studied as part of two post-market studies.

The information included in this document is intended to assist healthcare care decision makers in coverage evaluations and is in accordance with the National Association of Managed Care Physicians (NAMCP) Format.

This dossier should be used only by the intended health plan, and its distribution and/or duplication is prohibited.

Please direct comments and questions to:
Nevro Corp.
Medical Affairs
[redacted]

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1.0 BURDEN OF ILLNESS

1.1 Clinical Characteristics and Presentation of Medical Condition

The Senza spinal cord stimulator is FDA approved as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. The Senza spinal cord stimulator has proven safety and effectiveness data for the aid in the management of chronic intractable pain of the trunk and/or limbs. The Senza SCS is FDA approved, for expanded use, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of chronic intractable pain of lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy The safety and effectiveness of Senza SCS for aid in the management of painful diabetic neuropathy (PDN) in patients with symptoms refractory to conservative treatment is currently being studied as part of a post-market study. Refer to **Table 1-1** for a brief overview of information about Senza.

Table 1-1. Table of Highlights for Senza

	Key Information
Revision dates (to this table)	4/13/2022
Manufacturer name	Nevro Corp.
Approved product name	Senza® Senza II™ Senza Omnia™
Approved use and indication	The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems are indicated as aids in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy. The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery).
Original FDA Pre Market Approval	May 13, 2015
Expanded use FDA Pre Market Approval (PDN)	July 15, 2021
Expanded use FDA Pre Market Approval (Non-Surgical Back Pain)	January 18, 2022
Completed trials (related to approved indication)	SENZA-RCT SENZA-EU SENZA-PDN SENZA-NSRBP
Painful Diabetic Neuropathy Clinical	SENZA-PDN, NCT03228420 (Petersen 2021) • Enrollment dates: August 2017 to August 2019

Endpoints and Outcomes	• Key endpoints: ○ Primary: Composite outcome of ≥50% pain relief (measured by VAS pain scores) and no worsening in neurologic deficit at 3 months ○ Secondary: Difference between the treatment groups lower limb pain VAS score ≤3 cm; difference between the treatment groups in crossover rates; difference between the treatment groups in responder rates; difference between the treatment groups in proportion of remitters; difference between the treatment groups in overall improvement from baseline in neurological assessment; difference between the treatment groups in changes in HRQoL (measured by EQ-5D-5L) ○ Other endpoints: difference between the treatment groups in changes in health-related quality of life (measured by PSQ-3, GAF, 6-minute walk test, and patient satisfaction); difference between groups in opioid and healthcare utilization Sample size: N=216 patients
Non-Surgical Refractory Back Pain (NSRBP) **Clinical Endpoints and Outcomes**	SENZA-NSRBP, NCT03680846 (Kapural 2022) • Enrollment Dates: September 2018 to January 2020 • Key Endpoints ○ Primary: Difference between treatment groups in responder rate at 3 months. Responder is defined as a subject who has at least 50% reduction in pain from Baseline as assessed by a 10 cm Visual Analog Scale ○ Secondary: Change in Disability as Measured by Oswestry Disability Index; Percentage change from baseline in back pain intensity (as assessed by VAS); Changes in Quality of Life (QOL) as measured by EuroQol EQ-5D-5L questionnaire; Global impression of change; Change from baseline in opioid equivalent medication usage in each group; Neurological assessment; Incidences of adverse events Sample size: N=211 patients
Site of care settings of product use	SCS Trials: • Physician Office (POS 11) • Ambulatory Surgery Center (POS 24) • Outpatient Hospital Department (POS 22) SCS Permanent Implants: • Ambulatory Surgery Center (POS 24) • Outpatient Hospital Department (POS 22)
Key Product Attributes	• Only spinal cord stimulator that utilizes 10 kHz High-Frequency SCS mechanism that demonstrated a substantial clinical improvement in pain relief in chronic back and leg pain compared to traditional 2 – 1,200 Hz SCS treatment. • Unique mechanism of action that is paresthesia-independent. This results in no driving restrictions or impact on sleep that enables average daily use of 24 hours vs 17 hours with traditional SCS. • Allows for anatomical placement of the leads (typically at the T9–T10 vertebral range), thereby eliminating the need for intraoperative mapping. Minimal additional training is required (other aspects of procedure are consistent with today's procedural techniques) • Rechargeable battery is designed for 10-year lifespan. • Evidence-supported long-term outcomes related to clinical and humanistic benefits for patients failing CMM. • Centers for Medicare and Medicaid Services (CMS) created a new device category (C1822) in 2016 for 10 kHz therapy: HCPCS code C1822 is based on a clinical trial that demonstrated that a high frequency spinal cord stimulator operated at 10,000 Hz and paresthesia-free provides a substantial clinical improvement in pain management versus a low-frequency spinal cord stimulator

Key: cm – centimeter; FDA – Food and Drug Administration; GAF – Global Assessment of Functioning; HRQoL – health-related quality of life; ITT – intention-to-treat; PDI – Pain Disability Index; PDN – painful diabetic neuropathy; PPN – painful polyneuropathy; PDUFA – Prescription Drug User Fee Act; PSQ-3 – Pain and Sleep questionnaire; sBLA – supplemental Biologics License Application; SF-MPQ-2 – short-form McGill pain questionnaire; sNDA – supplemental New Drug Application; US – United States; VAS – visual analog scale.

Sources: CDC 2020; Hicks 2019; Pop-Busia 2017; Veves 2008

2.0 PRODUCT INFORMATION

2.1 Technology Description and Characteristics

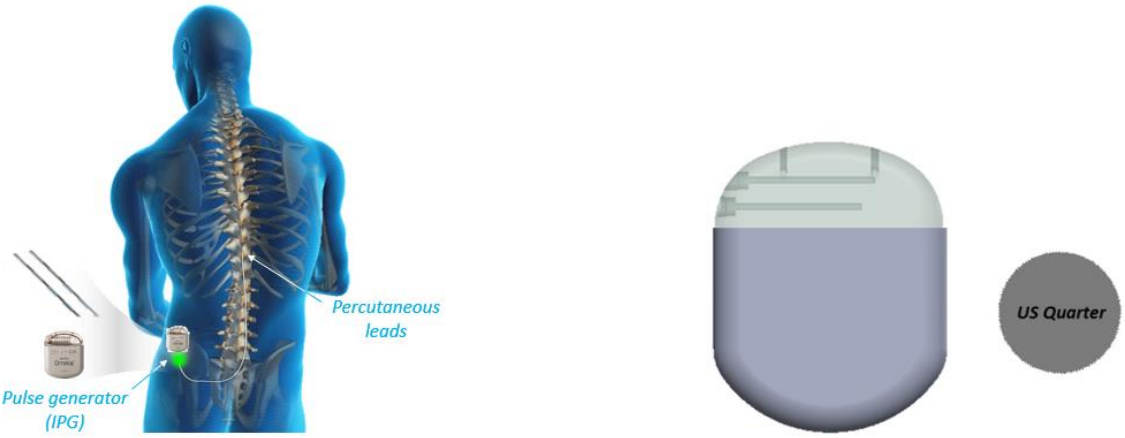
Product Details

The Senza SCS (Senza®, Senza II™, and Senza Omnia™ (Senza) Spinal Cord Stimulation (SCS) Systems) are neuromodulation devices designed to deliver electrical stimulation for the treatment of chronic intractable pain of the back, trunk and/or limbs **(Figure 2-1)**. The Senza, Senza II, and Senza Omnia Systems are implantable systems and deliver stimulation using implantable leads and a rechargeable, implantable pulse generator (IPG). The IPG is implanted in a subcutaneous pocket and is capable of stimulating the spinal cord nerves when used with one or more leads. The IPG is controlled by a Patient Remote and/or the Clinician Programmer. Other components of the Senza, Senza II, and Senza Omnia Systems include an external Trial Stimulator capable of delivering the same stimulation as the IPG, Lead Extensions, Adaptors, Charger and charging system, operating room (OR) cables and surgical accessories.

Senza is minimally invasive, reversible, and typically prescribed for the treatment of pain of the back, trunk, and/or limbs. Stimulation frequencies in the range of 2 Hz to 1,200 Hz are indicated for paresthesia-based therapy, and the system must be configured to produce paresthesia that overlaps the painful area. Stimulation at 10 kHz is indicated as paresthesia-independent therapy and provides pain relief without the production of parasthesias. The device is rechargeable and is designed for a 10-year battery life.

Additionally, Nevro keeps a global database, HFX Connect™, a General Data Protection Regulation (GDPR) compliant, secure, web-based platform that is used to collect and provide patient-reported outcomes after the device implant. The web-based platform tracks all patient interactions with Nevro to help to maximize patient satisfaction and provide outcome analytics to the physicians using Nevro SCS System.

Figure 2-1. Senza IPG Placement and Relative Size



Key: IPG – implantable pulse generator; US – United States.

Source: Data on file 2020a

Procedure Profile

The physicians providing SCS therapy with the Senza SCS should be experienced in the diagnosis and treatment of chronic pain and have proper surgical and clinical training. Senza allows for anatomical placement of the leads, thereby eliminating the need for intraoperative mapping when used to deliver 10 kHz stimulation. Currently there are over 5,000 primarily Interventional Pain/Anesthesiology and Neurosurgeons with the proper training and credentialing to implant a Senza SCS device.

The first step of SCS therapy is a trial phase, typically, the lead is placed in the patient, and the proximal end is externalized and connected to the Trial Stimulator using a connecting cable, which is referred to as the OR Cable.

Paresthesia mapping is not required for 10 kHz frequency programming. If frequencies up to 1,200 Hz are used for programming, paresthesia mapping is needed. When the trial is over, the lead is removed from the patient.

The trial period of the therapy may last between three and fourteen days providing the patient and physician an opportunity to experience the system on a temporary basis and evaluate how well the device may work on a permanent basis. Typically, a successful trial is described as achieving 50% pain reduction from baseline.

If the trial is successful, the patient will move to the implant phase when a permanent system is implanted. The placement of the permanent system includes placing new permanent leads as well as the implantable pulse generator (IPG).

Conventional SCS – Mechanism of Action for Traditional Frequency Stimulation (2 – 1,200 Hz)

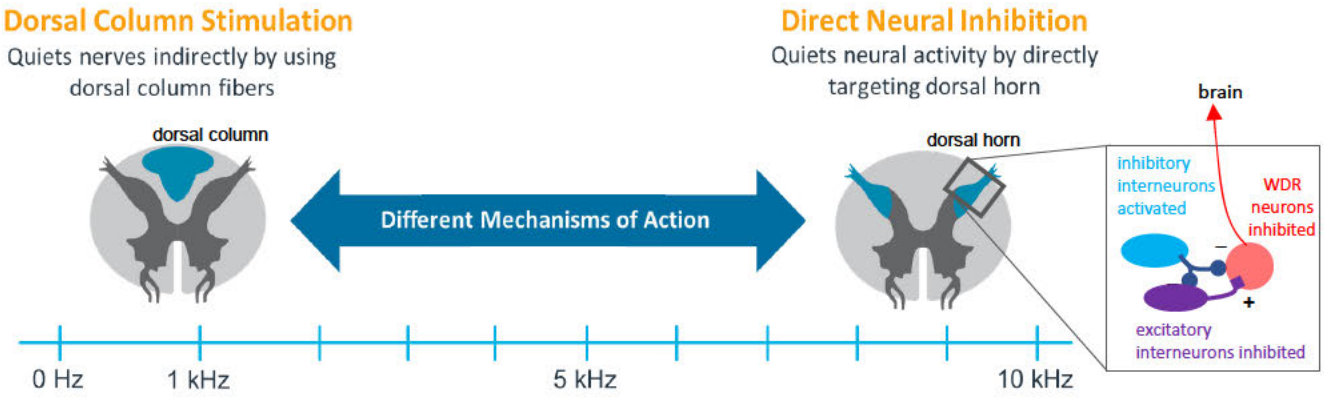
SCS is an approved treatment option for patients with refractory chronic pain. Annually, more than 80,000 US adults receive SCS devices (Data on file 2019). Conventional SCS involves short-duration current or voltage pulses delivered at a constant frequency (2−1,200 Hz) via an epidural electrode. This action excites axons in the dorsal column, whose primary function is to transmit non-nociceptive sensory information from body regions up to the brain. Stimulation of the dorsal column axons yields both a sensory paresthesia and ostensibly, indirect modulation of the spinal dorsal horn (a site of pain processing and generation). Stimulation frequencies in the range of 2−1,200 Hz are indicated for paresthesia-based therapy, and the system must be configured to produce paresthesia that overlaps the painful area (Zhang 2014).

Senza – Mechanism of Action for High-Frequency Stimulation (10 kHz)

Senza has a novel mechanism of action using HFX (High-Frequency 10 kHz) therapy. It delivers paresthesia-independent stimulation at 10 kHz (Physician Implant Manual). Senza may be programmed to deliver either, or both, low frequency (2–1,200 Hz) SCS and high frequency (HF; 10 kHz) SCS, to take advantage of the following mechanisms (**Figure** 2-2) (Al-Kaisy 2014; Linderoth 2006):

- **Dorsal column stimulation**, a paresthesia-based therapy via the low-frequency (2–1,200 Hz) stimulation of the dorsal columns, the mechanism used by other SCS systems
- **Direct neural inhibition of the dorsal horn**, which is not observed using SCS at frequencies ≤5 kHz (**Figure 2-3**). HF10 SCS can drive dorsal horn inhibitory neurons without activating dorsal column axons. This direct neural inhibition without dorsal column activation obviates the paresthesia that patients experience with lower frequency stimulation devices (Lee 2020)

Figure 2-2. Differentiating Mechanism of Action for HF Stimulation

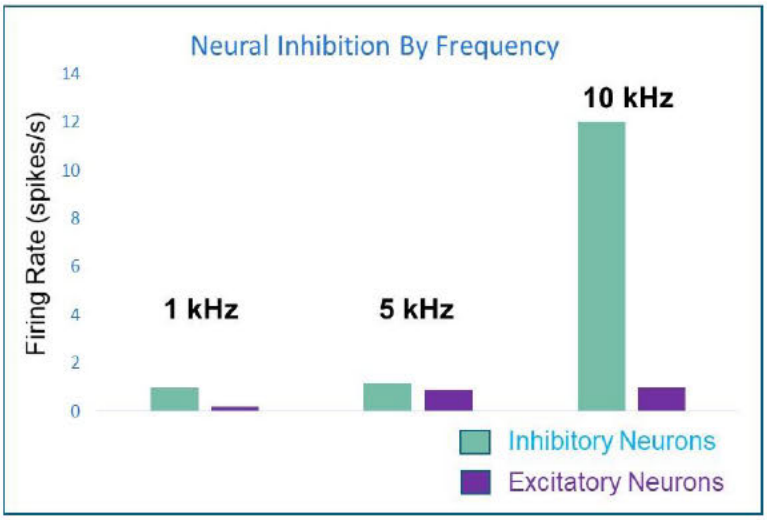


At low frequency (relatively high amplitude), dorsal column f bers are stimulated. These dorsal column fibers synapse onto the inhibitory interneurons and activate them, triggering the release of inhibitory neurotransmitters (e.g., GABA) to the WDRs, which in turn are hyperpolarized, subsequently reducing pain signals to the brain. At high frequency (>5 kHz), the dorsal horn is targeted, not the dorsal column. High-frequency 10 kHz may permeate the superficial dorsal horn and directly inh bit superficial dorsal horn pain circuitry (pain-projecting WDR neurons).

Key: GABA – Gamma aminobutyric acid; Hz – Hertz; kHz – kilohertz; WDR – wide dynamic range.

Source: Lee 2020

Figure 2-3. Excitatory and Inhibitory Activation at Different Frequencies



Key: kHZ – kilohertz; s – seconds.
Source: Lee 2018

Data from an ongoing, randomized controlled trial shows that Senza can provide improved pain relief compared to conservative (i.e., non-surgical) medical management in the treatment of patients with PDN (see **Section 3.0** for additional information on the Senza-PDN clinical trial).

Table 2-1. Product Information for Senza

	Product Information	
Approved product name	Senza®, Senza II™, Senza Omnia™	
Approved use and indication	As an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain	
PDN Indication	As an aid in the management of chronic intractable pain of the limbs, including unilateral or bilateral pain, associated with diabetic neuropathy	
NSRBP Indication	The Senza®, Senza II™ and Senza Omnia™ neuromodulation systems, when programmed to include a frequency of 10 kHz, are indicated as aids in the management of non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery).	
Original FDA Pre Market Approval	May 13, 2015	
FDA approval for expanded indication (PDN)	July 16, 2021	
FDA approval for expanded indication (NSRBP)	January 18, 2022	
CPT Procedure codes	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

	Product Information		
	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	
	63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	
	63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver	
	63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	
	63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	
Level II HCPCS Codes	C1822	Pulse Generator	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	C1820	Pulse Generator	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1778	Leads	Lead, neurostimulator (implantable)
	C1897	Trial Leads	Lead, neurostimulator, test kit (implantable)
	C1883	Lead Extension	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
	C1787	Patient Programmer	Patient programmer, neurostimulator
	L8687	Pulse Generator	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8680	Leads	Implantable neurostimulator electrode, each
	L8681	Patient Programmer	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8689	External Recharge	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
Potential ICD-10 diagnosis codes for PDN Indication	E08.4	Diabetes mellitus due to underlying condition with neurological complications	
	E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified	
	E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy	
	E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy	
	E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy	
	E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy	
	E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication	
	E10.4	Type 1 diabetes mellitus with neurological complications	
	E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified	
	E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	
	E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy	
	E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	
	E10.44	Type 1 diabetes mellitus with diabetic amyotrophy	
	E10.49	Type 1 diabetes mellitus with other diabetic neurological complication	

	Product Information	
	E11.4	Type 2 diabetes mellitus with neurological complications
	E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
	E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
	E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
	E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
	E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
	E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
	E13.4	Other specified diabetes mellitus with neurological complications
	E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
	E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
	E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
	E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
	E13.44	Other specified diabetes mellitus with diabetic amyotrophy
	E13.49	Other specified diabetes mellitus with other diabetic neurological complication
Potential ICD-10 diagnosis codes for NSRBP Indication	M51.35	Other intervertebral disc degeneration, thoracolumbar region
	M51.36	Other intervertebral disc degeneration, lumbar region
	M51.06	Intervertebral disc disorders with myelopathy, lumbar region
	M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
	M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
	M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
	M51.24	Other intervertebral disc displacement, thoracolumbar region
	M51.26	Other intervertebral disc displacement, lumbar region
	M54.89	Other Dorsalgia
	M54.9	Dorsalgia, unspecified
	M54.40	Lumbago with sciatica, unspecified side
	M54.41	Lumbago with sciatica, right side
	M54.42	Lumbago with sciatica, left side
	M54.15	Radiculopathy thoracolumbar region
	M54.16	Radiculopathy lumbar region
	M54.17	Radiculopathy, lumbosacral region
	M46.07	Spinal stenosis, lumbar region
	M48.06	Spinal stenosis, lumbosacral region
	M48.35	Traumatic spondylopathy, thoracolumbar region
	M48.36	Traumatic spondylopathy, lumbar region
	M48.37	Traumatic spondylopathy, lumbosacral region
	M48.8X5	Other specified spondylopathies, thoracolumbar region
	M48.8X6	Other specified spondylopathies, lumbar region

	Product Information	
Potential ICD-10 diagnosis codes for NSRBP Indication	M48.8X7	Other specified spondylopathies, lumbosacral region
	M49.85	Spondylopathy in diseases classified elsewhere, thoracolumbar region
	M49.86	Spondylopathy in diseases classified elsewhere, lumbar region
	M49.87	Spondylopathy in diseases classified elsewhere, lumbosacral region
	M47.10	Other spondylosis with myelopathy, site unspecified
	M47.16	Other spondylosis with myelopathy, lumbar region
	M47.25	Other spondylosis with radiculopathy, thoracolumbar region
	M47.26	Other spondylosis with radiculopathy, lumbar region
	M47.27	Other spondylosis with radiculopathy, lumbosacral region
	M47.815	Spondylosis without myelopathy or radiculopathy, thoracolumbar region
	M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region

The Senza Physician Implant Manual is available at: https://www.nevro.com/English/us/providers/product-manuals/default.aspx
Key: FDA – Food and Drug Administration

2.2 Diabetic Neuropathy Disease Description

2.3 Epidemiology

In the United States (US), there are 34.1 million (13.0%) adults living with diabetes (CDC 2020). The most prevalent chronic complication of diabetes is diabetic peripheral neuropathy (Hicks 2019; Pop-Busui 2017). Prevalence estimates vary (6%−51%) depending on diabetes type, disease duration, and glucose control; overall, approximately 50% of adult with diabetes will experience neuropathy in their lifetime. Approximately 40% to 50% of adults with diabetic neuropathy will experience PDN (6.8 to 8.5 million US adults) (Veves 2008).

Risk factors for PDN align with factors that increase the risk of any diabetic neuropathy and are generally associated with complications of diabetes disease progression; these include hyperglycemia, disease duration, age, hypertension, dyslipidemia, and obesity (Papanas 2015). Every 1% increment increase in hemoglobin A1c (HbA1c) is associated with approximately 10% to 15% higher frequency of diabetic peripheral neuropathy (Papanas 2015; Ziegler 2014).

2.4 Unmet Need

Diabetic neuropathies are a heterogeneous group of conditions that affect the nervous system and present with various clinical manifestations (Hicks 2019; Pop-Busui 2017). Chronic distal symmetric polyneuropathy (DSPN) is the most common diabetic neuropathy, accounting for roughly 75% of neuropathies. It is defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in patients with diabetes with no other etiology. Many patients with DSPN experience Painful Diabetic Neuropathy (PDN), which is described as burning, tingling, shooting, sharp and lancinating pain, initially starting in both feet, with the potential to progress up to the legs (often to the knees) and to the hands over time (Gore 2005; Pop-Busui 2017).

Several approved treatment options exist for PDN, many being pharmacologic in nature (anticonvulsants, antidepressants, opioids, etc.) and have limitations in terms of efficacy and side effects. Current PDN treatments include neuropathic pain medications, such as gabapentinoids, serotonin-norepinephrine reuptake inhibitors (antidepressants), tricyclic antidepressants, opioids, and topical solutions (Pop-Busui 2017; Bril 2011). High-quality randomized clinical trials (RCTs) have demonstrated limited efficacy of these medications with high incidence of adverse effects. Gabapentinoids may increase the risk of respiratory depression, a serious concern for patients taking opioids or with underlying respiratory impairment (“Gabapentin and Risk,” 2018; Meisenberg 2017; Eipe 2011). In addition to the potential for opioid dependence. Systematic review and meta-analysis of neuropathic pain medication RCTs reported a number needed to treat ranging from 3.6 to 7.7, with a number needed to harm ranging from 11.8 to 25.6 (Finnerup 2015).

Gabapentin and pregabalin are commonly prescribed for PDN, but long-term adherence can be poor, with more than 60% of patients discontinuing by 6 months (Yang 2015). Duloxetine reveals a similar pattern, with 50% discontinuing by 6 months (Yang 2015). Most of these patients do not switch to an alternative therapy, leaving their progressive neuropathic pain condition un-treated. This represents a large patient population with significant unmet needs.

Moreover, from a cost impact standpoint, direct costs have been reported to be 4x higher for patients with PDN vs patients with diabetes alone (Sadosky 2015). Severe pain in PDN patients was associated with increased costs and higher clinical utility. When compared to the PDN cohort, patients with severe PDN had higher rates of emergency department visits and hospitalizations respectively (Sadosky 2015). A retrospective claims analysis using the MarketScan database found that baseline costs associated with PDN patients were 20% higher than patients with diabetes alone (Kiyani 2020).

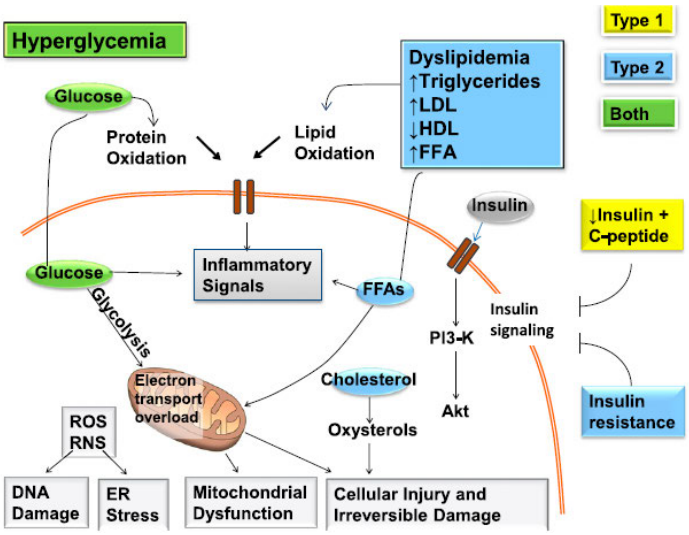
The Senza SCS 10 kHz treatment is the first and only FDA- authorized SCS treatment with 10 kHz SCS for PDN as an effective and safe alternative to conventional medical management of PDN. It is important to note that Nevro has completed their Senza SCS for PDN primary endpoint analysis, 6-month and 12-month follow-up visits for all patients and their primary endpoint of meaningful pain relief without worsening of baseline neurological deficits.

2.4.1 *Pathophysiology*

The cause of diabetic neuropathy remains unknown; however, it is thought to be multifactorial; oxidative stress and inflammation, in the presence of metabolic dysfunction, lead to nerve cell damage (**Figure 2-4**) (Pop-Busui 2017). While progress in understanding its pathophysiology has been made recently, treatment options that target

the progression or reversal of diabetic neuropathy are lacking, and current treatment options remain largely pharmacologic in nature.

Figure 2-4.1 Mechanisms of Diabetic Neuropathy



Note: Factors linked to type 1 diabetes (shown in yellow), type 2 diabetes (shown in blue), and both (shown in green) lead to DNA damage, ER stress, mitochondrial dysfunction, cellular injury, and ultimately, irreversible damage. Pathway importance varies based on cell type, disease profile, and time.

Key: Akt – protein kinase B; DNA – deoxyribonucleic acid; ER – endoplasmic reticulum; FFA – free fatty acids; HDL – high-density lipoprotein; LDL – low-density lipoprotein; PI3-K – phosphatidylinositol-3 kinase; RNS – reactive nitrogen species; ROS – reactive oxygen species.

Figure reproduced with permissions from the ADA; more information is available at: https://www.diabetesjournals.org/content/license

Source: Pop-Busui 2017

2.4.2 *Clinical Presentation*

PDN is characterized by tingling, burning, or shooting pain in the extremities and may occur with paresthesias (Hicks 2019; Pop-Busui 2017). It presents in various combinations, can cause hyperalgesias, and is generally worse at night. The average age of onset is >60 years of age (Hoffman 2015; Sadosky 2013).

Diabetic neuropathy is typically an irreversible disease (Hicks 2019). Complications include chronic pain, foot ulcerations, along with subsequent infections and amputations, which are a mortality predictor (Hicks 2019; Pop-Busui 2017). To avoid the complications of diabetic neuropathy, the American Diabetes Association recommends that all adult patients are screened for diabetic neuropathy at the time of diabetes (type 2) diagnosis and annually thereafter (Hicks 2019; Pop-Busui 2017). Screening includes medical history, a pinprick or temperature sensation test, vibration sensation test, and visual inspection of the feet with a monofilament sensory test.

2.4.3 *Clinical and Humanistic Burden*

Clinical Burden

The clinical burden of diabetic neuropathy is well-documented, and studies have shown poor outcomes in regard to ulcers, infections, amputations, pain management, and adherence.

Compared to the general population, individuals with diabetic neuropathy are at an increased risk of chronic pain, foot ulcerations, foot infections, and amputations. Foot ulceration, which is most commonly caused by chronic distal symmetric polyneuropathy, can lead to infections and amputations.

- An estimated 92% of foot ulcer hospital admissions are associated with diabetic neuropathy, and infections account for 89.4% of these; furthermore, 83% of all major amputations in the US are due to diabetes (Hicks 2016).
- According to the ADA, an estimated 14% to 24% of patients with a foot ulceration will require amputation (ADA 1999).

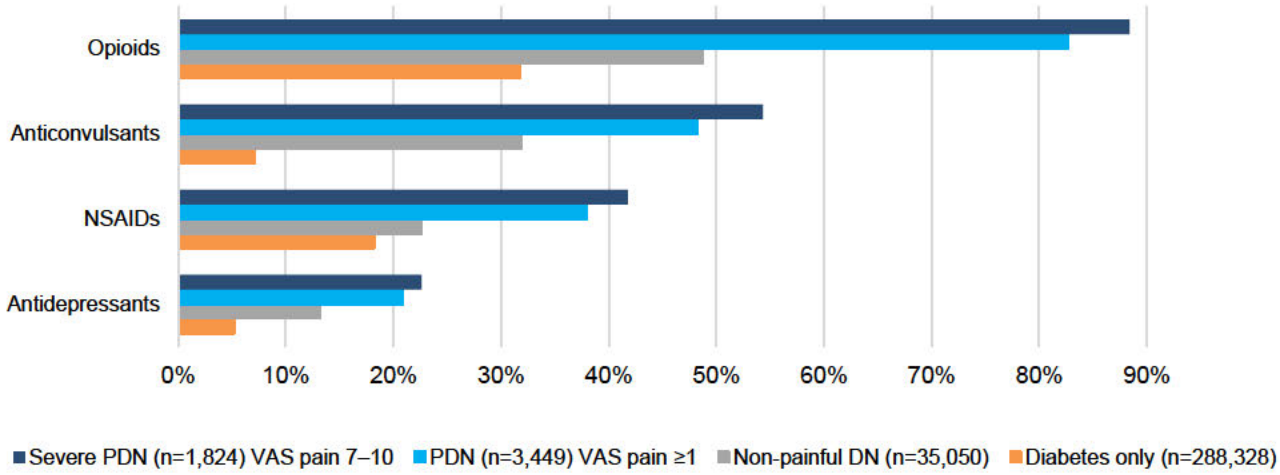
- A retrospective claims MarketScan database analysis from January 2010 to December 2015 found amputation risk in the PDN subgroup was 16.24 times that of diabetic controls (95% CI [2.15, 122.72], *P*=0.0003), and within 1 year, 87% more patients with PDN experienced lower-extremity infections (95% CI [1.43, 2.46], *P*<0.0001) (Kiyani 2020).

Furthermore, people with chronic distal symmetric polyneuropathy are at increased risk of falls and fractures due to a loss of sensation and proprioception, and pain, which result in lack of balance, repetitive injuries, and falls (Brown 2015; Schwartz 2002; Wallace 2002). Patients with neuropathic pain may experience an exaggerated pain response to painful stimuli and pain with contact of everyday items such as socks, shoes, and bedding, making pain management an important aspect of treatment (Pop-Busui 2017; Staudt 2020). Kiyani and colleagues found 2.2% of patients with PDN had falls and fall-related injuries compared with 1.1% of control patients with diabetes (*P*<0.0001) within 2 years (Kiyani 2020).

With conservative medical management (CMM) (i.e., non-surgical) options, a high proportion of patients experience inadequate pain control (Staudt 2020). Inadequate management of PDN complications can lead to pain, and patients with PDN are more likely to receive treatment for pain management than those without PDN.

- Using the Humedica Electronic Medical Record (EMR) database, Sadosky et al. conducted a claims analysis (diabetes alone, n=288,328; non-painful diabetic neuropathy [DN], n=30,050; PDN, n=3,449; and severe PDN, n=1,824) and found that patients with PDN and severe PDN were more likely to receive any pain-related medications compared to patients with diabetes alone or non-painful DN. The majority of medications were opioids (any pain related medication: 42.8%, 65.9%, 91.4%, 94.7%; opioids: 31.7%, 48.7%, 82.7%, 88.4% for diabetes alone, non-painful DN, PDN, and severe PDN, respectively) (**Figure 2-**) (Sadosky 2015).

Figure 2-4.3. Sadosky et al. Drug Class Usage for 12-Month Period Following Diagnosis

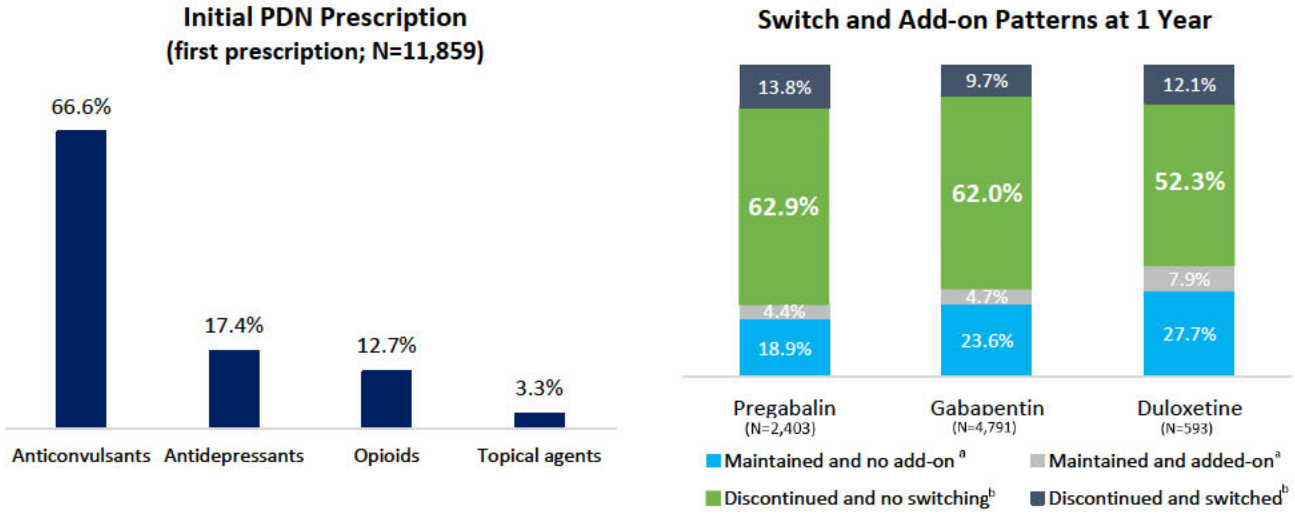


Key: DN – diabetic neuropathy; NSAID – non-steroidal anti-inflammatory drug; PDN – painful diabetic neuropathy; VAS – visual analog scale.
Source: Sadosky 2015

- Kiyani reported that patients with PDN, compared to patients with diabetes alone, had 200%, 356%, and 224% odds of taking opioids, anticonvulsants, and antidepressants, respectively (Kiyani 2020).
- Opioids, which are used for treatment of patients with refractory symptoms, come with the risks of addiction, abuse, sedation, and other complications, while other highly utilized treatment options (e.g., topical agents) lack adequate pain relief (Finnerup 2015; Pop-Busui 2017).
- A retrospective study of treatment patterns using data from a commercial and Medicare claims database (between 2006 and 2011) examined adherence rates at 1 year in 12,704 patients with PDN. The majority of patients (62.9%, 62.0%, and 52.3% for pregabalin, gabapentin, and duloxetine, respectively) discontinued treatment and did not switch to an alternative therapy (**Figure 2-**). Up to 50% of patients discontinued treatment within the first 90 days, which may be reflective of poor tolerability because many adverse events (AEs) emerge soon after therapy initiation (Yang 2015). Additionally, approximately 2/3 (66.6%) of patients were initiated on an anticonvulsant, followed by antidepressants (17.4%); however,

12.7% of patients received an opioid as their first prescription (**Figure 2-**), and the most commonly added agent to anticonvulsants was opioids (Yang 2015).

Figure 2-4.4. Initial Prescriptions and Switch and Add-On Therapy Patterns at 1 Year for Patients With PDN



Note: Anticonvulsants included gabapentin (45.0%) and pregabalin (21.6%); antidepressants included amitriptyline (6.6%), desipramine (0.1%), duloxetine (5.2%), nortriptyline (4.6%), venlafaxine (0.9%); opioids included morphine (0.6%), oxycodone (2.4%), and tramadol (9.8%); topical agents included lidocaine (3.3%).

[a] Switching was defined as discontinuation of initial treatment and starting a new medication.

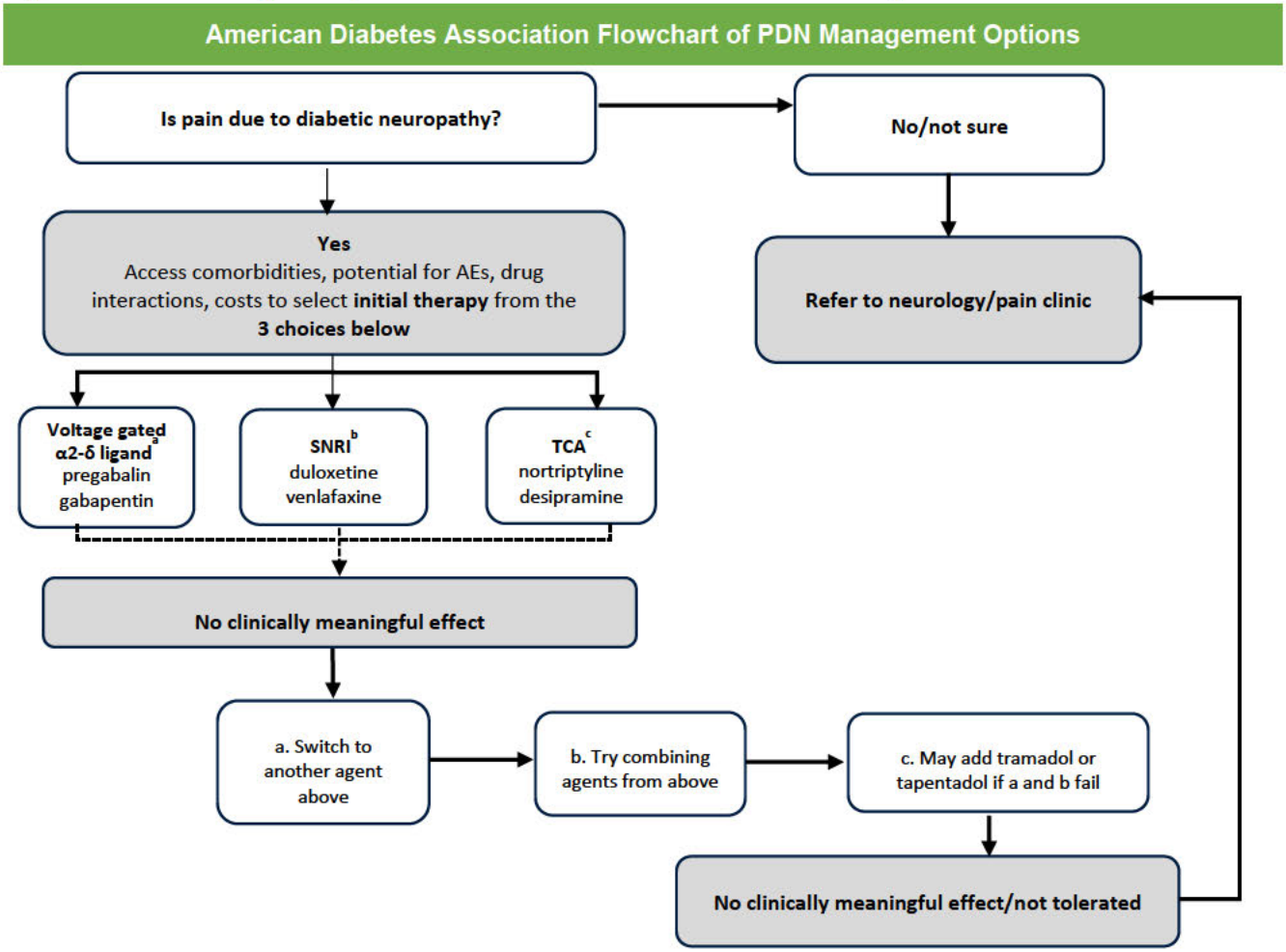
[b] Add-on was defined as using another pain medication in additional to the initial treatment.

Key: N – number; PDN – painful diabetic neuropathy.

Source: Yang 2015

While significant burden exists for PDN, guideline recommendations are highly variable. These variable guideline recommendations beginning with pharmacotherapy (non-opioid classes as single or part of combination treatments), then adding opioids and then neuromodulation therapies (e.g., SCS). While there are numerous CMM options available, pain management remains a challenge. **Figure 2-** is a summary of key guideline management options (Bril 2011; Pop-Busui 2017).

Figure 2-4.6. Summary of Key Guideline Recommnedation for PDN Management



[a] Pregabalin is FDA-approved for PDN, whereas gabapentin is not.

[b] Duloxetine is FDA-approved for PDN, whereas venlafaxine is not.

[c] No TCAs are FDA-approved for PDN.

Key: AE – adverse event; PDN – painful diabetic neuropathy; SCS – spinal cord stimulation; SNRI – serotonin-norepinephrine reuptake inhibitor; TCA – tricyclic antidepressants.

Source: Bril 2011; Pop-Busui 2017

While there are numerous CMM options available for patients with PDN, pain management remains a challenge. There is a growing demand for alternative treatments for PDN, and HF10 (10 kHz) SCS therapy may improve pain management outcomes (Galan 2020; Yang 2015).

Humanistic Burden

Neuropathic pain can lead to interference with daily activities (e.g., inability to perform work or leisure activities), disability, psychosocial impairment, and reduced health-related quality of life (HRQoL) (Vileikyte 2009; Vileikyte 2003). Patients with PDN are also more likely to suffer from depression, lost productivity, and decreased quality of life (QoL) (Staudt 2020).

- A systematic literature review reported that patients with PDN experience interference with general activity, sleep, mood, walking, work, relationships, and enjoyment of life (Alleman 2015). On average, Brief Pain Inventory interference scores (range: 0−10; no interference to complete interference) for patients with PDN were 4.8 for overall pain interference, with walking ability and general activity subscales being most affected followed closely by sleep, mood, and enjoyment for life.
- Anxiety and depression are common in PDN patients due to the continuous pain, disruption of daily life, and treatment success uncertainty (Alleman 2015). An estimated 24.5% to 72.1% of PDN patients report symptoms of depression and/or anxiety.
- Painful symptoms cause impaired work productivity, with higher pain severity associated with higher disease burden. A cross-sectional study estimated 35% of PDN patients reported some level of work disruption due to pain, and approximately 59% of working patients reported being less productive at work at least some of the time. Pain-related work disruptions increased with pain severity. Roughly 14% of patients with mild pain reported work disruptions compared to 38% of patients with moderate pain, and 48% of patients with severe pain (Tölle 2006).

Successful pain treatment for patients with PDN has been shown to statistically improve scores on the Short-Form 36-Item Survey (SF-36) (specifically in physical functioning, bodily pain, mental health, sleep, and enjoyment of life subclasses), brief pain interference scores (general activity, mood, walking ability, social relations, sleep, enjoyment of life) and EQ-5D-5L scores in several randomized control trials (RCTs) (O'Connor 2009).

3.0 VALUE EVIDENCE SUPPORTING TECHNOLOGY (PDN)

Ongoing clinical trials show that treatment using the Senza SCS produces clinical and humanistic benefits for patients with chronic pain failing CMM (Al-Kaisy 2014, Kapural 2016). The 10 kHz SCS mechanism of Senza has demonstrated significant pain relief compared to traditional SCS, while reducing opioid burden in patients with refractory PDN.

This section currently contains clinical evidence that has been published and/or presented regarding the expanded indication recently approved by the FDA of Senza for aid in the management of PDN. This section also includes data from the original the pivotal clinical trial for Senza SCS approved use for aid in the management of chronic intractable pain of the trunk and/or limbs to demonstrate established safety.

Clinical Efficacy and Patient Outcomes

Completed Clinical Trial Study Description: Senza-PDN is a prospective, multicenter, open-label, RCT to evaluate the safety and efficacy of 10 kHz SCS plus CMM vs CMM alone in patients with PDN symptoms refractory to CMM. Enrolled patients were tracked from August 2017 to December 2022 (estimated end date).

Endpoints:

The primary endpoint is a composite of safety and efficacy, specifically the proportion of patients with ≥50% pain relief (measured via visual analog scale [VAS]) and no meaningful worsening in baseline neurological deficits at 3 months.

If the primary endpoint is met, hierarchical testing of secondary endpoints will be conducted. Secondary endpoints include the difference between treatment groups in the following: patients with a lower limb pain VAS score ≤3 cm, crossover rates, responder rates, remitter rates, overall improvement from baseline neurological function, HRQoL changes assessed via EQ-5D-5L and change from baseline in HbA1c. Other endpoints include HRQoL outcomes measured by Pain and Sleep Questionnaire (PSQ-3), Global Assessment of Functioning (GAF), and patient satisfaction scores and opioid and healthcare utilization.

Safety was assessed using AE monitoring and neurological assessment.

Methods:

Key Inclusion Criteria

Patients were included if they were ≥22 years of age upon enrollment with a PDN diagnosis (symptoms ≥12 months) and lower limb pain ≥5 cm on a 10 cm VAS, on a stable analgesic regimen, refractory to pregabalin or gabapentin and ≥1 additional analgesic therapy class.

Key Exclusion Criteria

Patients were excluded if they had HbA1c >10%, body mass index (BMI) >45 kg/m^2, upper limb pain intensity ≥3 cm, or >120 mg morphine equivalents in daily opioid dosage.

Study Design

Patients were identified and screened across 18 US sites and randomized 1:1 via concealed computer assignment to receive treatment with 10 kHz SCS+CMM or CMM alone. A random-sized block method by site and stratified by pain scores (VAS) and glycemic control (HbA1c) were used. Patients undergoing SCS treatment received a temporary trial stimulation with percutaneous leads positioned along T8−T11. If ≥50% pain relief was achieved, patients were eligible to undergo permanent SCS device implantation. Pre-defined study follow-up times are at 3, 6, 12, and 24. Patients were eligible for crossover at 6 months.

Sample Characteristics:

A total of 216 patients (10 kHz SCS+CMM, n=113; CMM alone, n=103) with PDN were randomized. Baseline patient characteristics are shown in **Table 3-1**. At 6 months, 92% (95/103) of patients remained in the CMM alone group and 81% (92/113) of patients in the 10 kHz SCS+CMM group. The mean age was 60.8 years and 63% of the patients were male. The mean lower limb pain VAS was 7.5 vs 7.1 in the 10 kHz SCS+CMM and the CMM alone groups, respectively. The majority of patients were on an anticonvulsant (78% vs 77%, 10 kHz SCS+CMM vs CMM alone, respectively), with the second highest utilized medication class being opioids (44% vs 43%, 10

kHz SCS+CMM vs CMM alone, respectively). At 6 months, 82% of patients in the CMM alone group crossed over to 10 kHz SCS+CMM, and no patients crossed over from 10 kHz SCS+CMM to CMM alone.

Table 3-1. Senza-PDN: Demographics and Baseline Characteristics (FAS)

Characteristic	10 kHz SCS+CMM (n=113)	CMM alone (n=103)
Age, years, mean (SD)	60.7 (11.4)	60.8 (9.9)
Male, n (%)	70 (62%)	66 (64%)
Race, n (%)		
White	87 (77.0%)	85 (82.5%)
Black/African American	18 (15.9%)	13 (12.6%)
Other	8 (7.1%)	5 (4.9%)
Type 1 diabetes	8 (7%)	3 (3%)
Type 2 diabetes	105 (93%)	100 (97%)
Duration of diabetes, years, mean (SD)	12.9 (8.5)	12.2 (8.5)
Duration of PN, years, mean (SD)	7.4 (5.7)	7.1 (5.1)
Lower limb pain VAS in cm, mean (SD)	7.5 (1.6)	7.1 (1.6)
<7.5 cm, n (%)	54 (48%)	57 (55%)
≥7.5 cm, n (%)	59 (52%)	46 (45%)
HbA1c, mean (SD)	7.3% (1.1%)	7.4% (1.2%)
<7.0% n (%)	46 (41%)	40 (39%)
≥7.0%, n (%)	67 (59%)	63 (61%)
BMI kg/m^2, mean (SD)	33.6 (5.4)	33.9 (5.2)
Severity of neuropathic pain		
DN4, mean (SD)	6.6 (1.7)	6.4 (2.0)
<4, n (%)	2 (2%)	7 (7%)
≥4, n (%)	111 (98%)	96 (93%)
mNSS, mean (SD)	6.8 (1.3)	6.9 (1.1)
mild (3−4), n (%)	2 (1.8%)	2 (2.0%)
moderate (5−6), n (%)	46 (40.7%)	33 (32.4%)
severe (7−9), n (%)	65 (57.5%)	67 (65.7%)
Pain medications		
Anticonvulsants		
gabapentin, n (%)	63 (56%)	50 (49%)
pregabalin, n (%)	25 (22%)	29 (28%)
Antidepressants		
SNRIs, n (%)	25 (22%)	29 (28%)
TCAs, n (%)	10 (9%)	14 (14%)
Opioids	50 (44%)	44 (43%)
Topical agents	11 (10%)	9 (9%)

[a] Standardized difference - Effect size (Cohen's d): ≥0.20 = small, ≥0.50 = medium, ≥0.80 = large.

Key: BMI – body mass index; CMM – conservative medical management; DN4 – Douleur Neuropathique; FAS – full analysis set; HbA1c – hemoglobin A1c; mNSS – modified Neuropathy Symptom Score; PN – peripheral neuropathy; SD – standard deviation; SNRI – serotonin-norepinephrine reuptake inhibitor; TCA – tricyclic antidepressant; VAS – visual analog scale.

Source: Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Published online April 05, 2021. doi:10.1001/jamaneurol.2021.0538

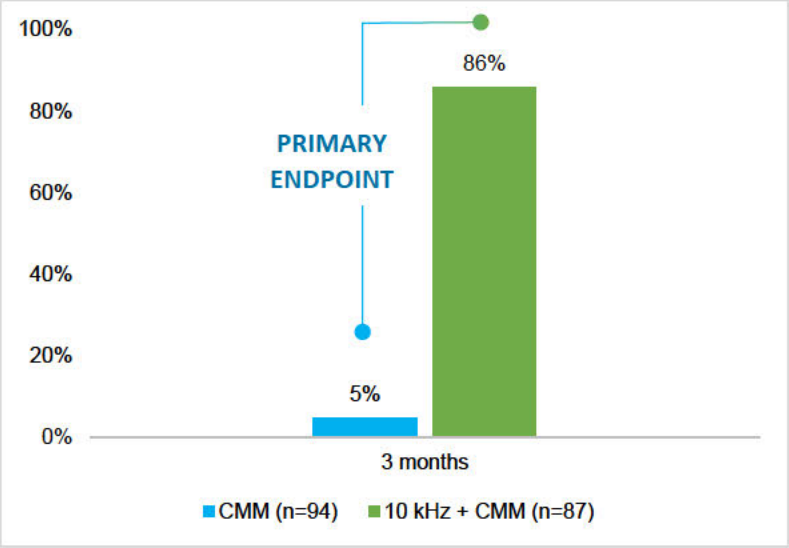
Results:

Primary Endpoint

In the per-protocol (PP) population (10 kHz SCS+CMM, n=87; CMM alone, n=94), 86% (75/87) of patients in the 10 kHz SCS+CMM group reported ≥50% pain relief with no worsening in neurological deficit at 3 months compared with 5% (5/94) of patients in the CMM alone group (P<0.001) (**Figure 3-1**). Results were similar in the intention-

to-treat (ITT) population with known status, which included trial failures (n=6) and patients who exited the study due to an AE (n=2) as non-responders in the 10 kHz SCS+CMM group; 78.9% (75/95) of patients in the 10 kHz SCS+CMM group reported ≥50% pain relief with no worsening in neurological deficit at 3 months compared with 5.3% (5/94) of patients in the CMM alone group (difference 73.6%, *P*<0.001).

Figure 3-1. Percentage of Patients Who Reported ≥50% Pain Relief With No Worsening in Neurological Deficit in the PP Population



Key: CMM – conservative medical management; kHz – kilohertz; PP – per-protocol.

Source: Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Published online April 05, 2021. doi:10.1001/jamaneurol.2021.0538

Secondary Endpoints

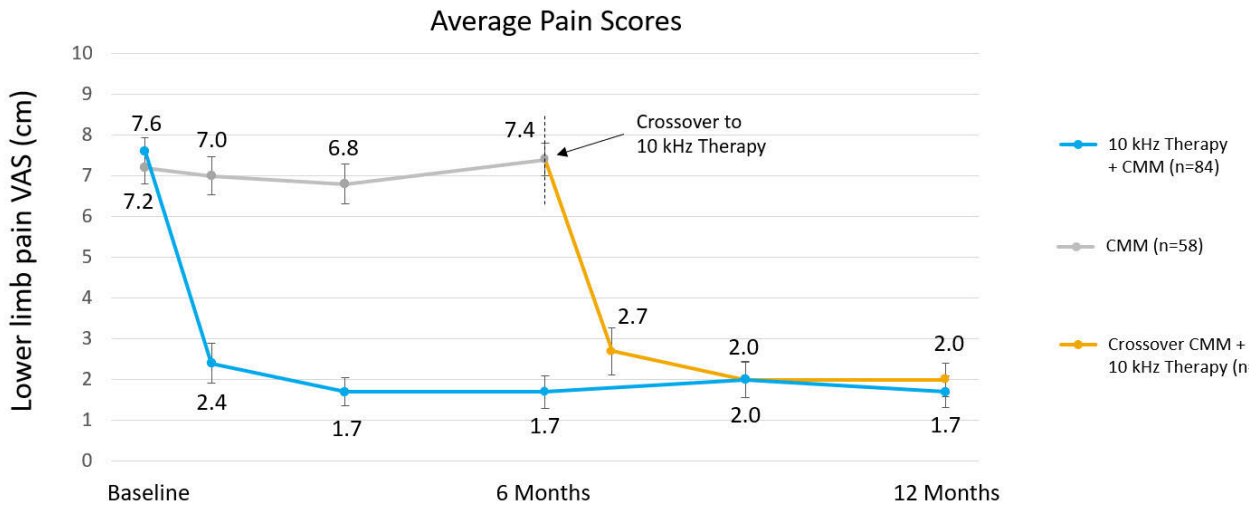
A summary of secondary endpoints is shown in **Source:** Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of high-frequency 10-kHz spinal cord stimulation for patients with painful diabetic neuropathy refractory to conventional treatments: 12-month results from a randomized controlled trial. Diabetes Care. 2021 Nov 29:dc211813.

Table 3-2.

Pain Scores

For patients in the 10 kHz arm, the mean lower limb pain VAS was 7.6 cm (95% CI 7.2–7.9) at baseline and 1.7 (95% CI 1.3–2.1) at 6 months and maintained at 12 months. This change represented 77.1% mean pain relief (95% CI 71.8-82.3; p < 0.0001). In addition, 86% (72 of 84) of patients in the 10 kHz were treatment responders, defined as patients with at least 50% pain relief compared to baseline. In contrast, patients in the CMM arm reported negligible change in mean lower limb pain VAS with a baseline mean of 7.0 cm (95% CI, 6.7-7.3) and a mean of 6.9 cm (95% CI, 6.5-7.3) at 6 months. At the 6-month follow-up, 81% (77 of 95) patients in the CMM arm opted to crossover to the 10 kHz arm. This crossover group experienced similar mean pain relief of 70.3% (95% CI, 63.4-77.1; p < 0.001) compared to the mean baseline and 6-month lower limb pain VAS of 7.2 cm versus 2.0 cm at 12 months. Eighty-four percent (84%) of the crossover group were also treatment responders. In addition to pain relief, researchers found maintained neurological improvements including improved sensory function, in 68% and 62% in patients originally in the 10 kHz arm and in the crossover group from CMM arm respectively. See Exhibit 4 for the outcome findings from the 12-month data. The pain scores of patients in the 10 kHz + CMM arm and the cross-over group are shown in **Figure 3-2**.

Figure 3-2. Pain Scores at 12 months



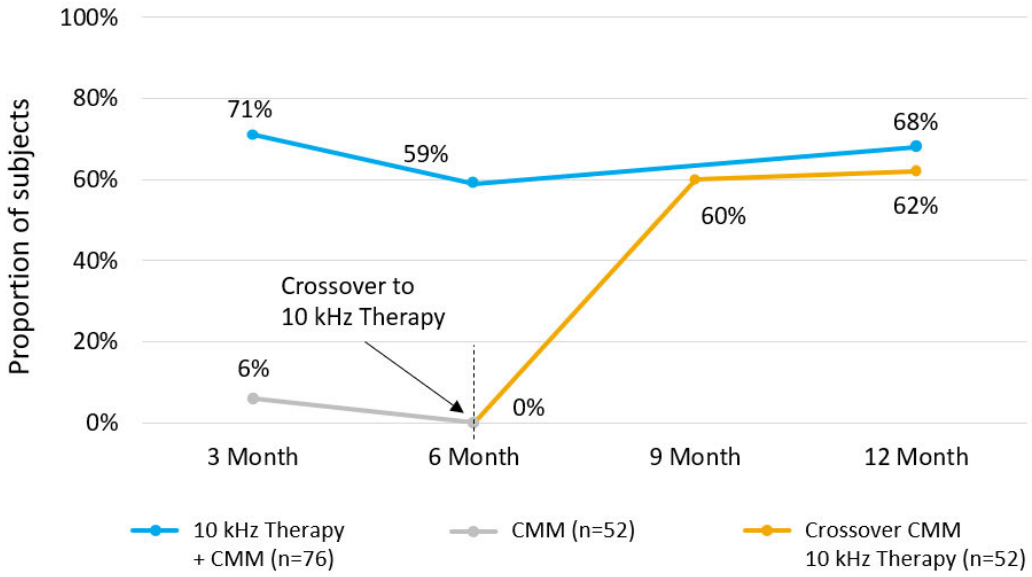
Key: cm – centimeter; CMM – conservative medical management; kHz – kilohertz; n – number; SCS – spinal cord stimulation; VAS – visual analog scale.

Source: Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of high-frequency 10-kHz spinal cord stimulation for patients with painful diabetic neuropathy refractory to conventional treatments: 12-month results from a randomized controlled trial. Diabetes Care. 2021 Nov 29:dc211813.

Neurological Assessment

Neurological examination improvements (measured by monofilament and pinprick tests) at 6 months were observed for 61.9% (52/84) of patients in the 10 kHz SCS+CMM group and 3.3% (3/92) of patients in the CMM alone group (difference 58.6%; *p*<0.001) **(Figure 3-3)**

Figure 3-3. Investigator assessed improvement compared to baseline in motor, sensory, or reflex function, without deterioration in any category



Source: Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of high-frequency 10-kHz spinal cord stimulation for patients with painful diabetic neuropathy refractory to conventional treatments: 12-month results from a randomized controlled trial. Diabetes Care. 2021 Nov 29:dc211813.

Table 3-2. Summary of Secondary Endpoints in the Per Protocol Population Over 12 Months

	10 kHz SCS+CMM		CMM Crossover to 10 kHz SCS after 6 months	
	Baseline	12 Months	Baseline	12 Months
HbA1c, n				
Mean (SD)	7.5% (1.2)	7.3% (1.2)	7.5% (1.1)	7.6% (1.2)
SF-MPQ-2, n				
Continuous pain, mean (SD)	5.2 (2.5)	1.6 (2.0)***	5.4 (2.6)	1.7 (1.6)***
Intermittent pain, mean (SD)	5.4 (2.5)	1.5 (1.9)***	5.6 (2.2)	1.4 (1.6)***
Neuropathic pain, mean (SD)	5.5 (2.0)	1.9 (1.7)***	5.4 (2.1)	1.9 (1.5)***
Affective descriptors, mean (SD)	4.0 (2.7)	1.0 (1.7)***	3.6 (2.7)	0.7 (1.1)***
Total, mean (SD)	5.1 (2.0)	1.6 (1.7)***	5.1 (2.0)	1.5 (1.3)***
BPI-DPN, n				
Pain severity index, mean (SD)	6.3 (1.8)	2.0 (1.8)***	6.3 (1.7)	2.3 (1.6)***
Pain interference index, mean (SD)	6.2 (2.1)	1.9 (2.0)***	5.9 (1.9)	2.1 (1.9)***
EQ-5D-5L, n				
Overall health VAS, mean (SD)	58.7 (18.7)	75.6 (18.6)***	58.1 (21.1)	75.4 (14.6)**
Index, mean (SD)	0.644 (0.145)	0.780 (0.123)***	0.630 (0.132)	0.761 (0.087)***
DQOL, n				
Satisfaction, mean (SD)	3.0 (0.7)	2.0 (0.8)***	3.0 (0.8)	2.2 (0.8)***
Impact, mean (SD)	2.5 (0.7)	1.8 (0.6)***	2.7 (0.7)	1.9 (0.5)***
Worry: social/vocational, mean (SD)	1.7 (0.7)	1.4 (0.6)***	1.7 (0.6)	1.3 (0.4)***
Worry: diabetes-related, mean (SD)	2.1 (0.8)	1.6 (0.7)***	2.3 (0.8)	1.8 (0.7)***
Total, mean (SD)	2.5 (0.6)	1.8 (0.6)***	2.6 (0.7)	1.9 (0.5)***
PSQ-3, n				
Trouble falling asleep due to pain, mean (SD)	7.0 cm (2.7)	2.8 cm (2.9)***	7.4 cm (2.2)	3.2 cm (2.9)***
Awakened at night by pain, mean (SD)	5.7 cm (3.1)	1.9 cm (2.5)***	6.7 cm (2.7)	2.8 cm (2.7)***

	10 kHz SCS+CMM		CMM Crossover to 10 kHz SCS after 6 months	
	Baseline	12 Months	Baseline	12 Months
Awakened in morning by pain, mean (SD)	5.1 cm (3.3)	1.7 cm (2.4)***	6.0 cm (2.9)	2.1 cm (2.5)**
GAF, n				
Mean (SD)	63.1 (16.4)	83.8 (10.6)***	62.1 (15.0)	79.0 (10.3)***
CGIC, n				
Better, Great Deal Better, %	-	79%	-	77%
Little, Somewhat, Moderately Better, %	-	20%	-	19%
No Change, Almost the Same, %	-	1%	-	4%
PGIC, n				
Better, Great Deal Better, %	-	73%	-	71%
Little, Somewhat, Moderately Better, %	-	23%	-	28%
No Change, Almost the Same, %	-	5%	-	2%
Participant Satisfaction, n				
Satisfied, Very Satisfied, %	-	94%	-	90%
Not Sure, %	-	5%	-	9%
Very Dissatisfied, Dissatisfied, %	-	1%	-	2%

Table 3-2: Outcomes assessed in the per-protocol population at baseline and 3 months. PSQ3: Pain and Sleep Questionnaire three-item index, EQ-5D-5L: 5 Level EuroQol 5-Dimensional questionnaire, DQOL: Diabetes Quality of Life measure, PGIC: Patient Global Impression of Change, CGIC: Clinician Global Impression of Change, BPI-DPN: Brief Pain Inventory for Painful Diabetic Peripheral Neuropathy, SF-MPQ-2: Short-Form McGill Pain Questionnaire version 2; *p < .05, **p < .01, ***p < .001

Key: cm – centimeter; CMM – conservative medical management; HbA1c – hemoglobin A1c; HRQoL – health-related quality of life; kHz – kilohertz; n – number; PP – per-protocol; SCS – spinal cord stimulation; SD – standard deviation; VAS – visual analog scale.

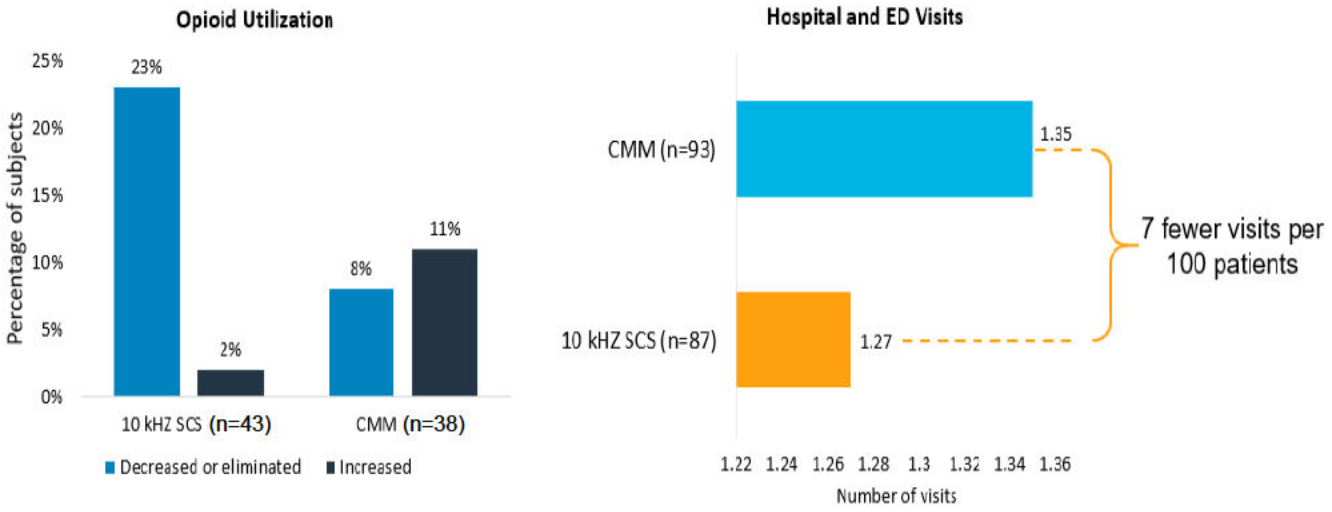
Source: Data on file 2021e.

Other Endpoints

Opioid Use and ED Visits

Opioid use and hospital and ED visit utilization decreased in patients on 10 kHz SCS+CMM compared to those on CMM alone (**Figure 3-3**) (Data on file 2020d). Opioid use decreased or was eliminated in 10/43 patients in the 10 kHz SCS+CMM group compared to 3/38 patients in the CMM alone group. Opioid use increased in 1/43 patients in the 10 kHz SCS+CMM group vs 4/38 patients in the CMM alone group.

Figure 3-3. Opioid and Healthcare Utilization



Key: CMM – conservative medical management; ED – emergency department; kHz – kilohertz; PDN – painful diabetic neuropathy; RCT – randomized controlled trial; SCS – spinal cord stimulation.

Source: Data on file 2020d

Safety

Infections/wound dehiscence requiring device removal occurred in 2 patients in the 10 kHz SCS+CMM group (2/90, 2.2%). There were 18 study-related AEs reported for the 10 kHz SCS+CMM group (**Table 3-3**). In the CMM alone group, no study-related AEs were reported, as the protocol did not require any specific CMM treatments.

Table 3-3. Senza-PDN Adverse Events and Infection Rates

	10 kHz Arm (0-6 months post implant) (n=90)	10 kHz Arm (6-12 months post implant) (n=90)	CMM Crossover to SCS (6 months post implant) (n=64)
Total Study-related AEs, n (# of subjects, %)	17 (13, 14.4%)	4 (4, 4.4%)	11 (10, 15.6%)
Rated as Serious AEs	2 (2, 2.2%)	1 (1, 1.1%)	4 (4, 6.2%)
Device Explant	2 (2, 2.2%)	1 (1, 1.1%)	2 (2, 3.1%)
Study-related AEs by type			
Infection	3 (3, 3.3%)	1 (1, 1.1%)	4 (4, 6.2%)
Incision or IPG discomfort	2 (2, 2.2%)	1 (1, 1.1%)	1 (1, 1.6%)
Wound dehiscence	2 (2, 2.2%)	--	--
Irritation from surgical dressings	2 (2, 2.2%)	--	--
Insufficient stimulation	--	--	2 (2, 3.1%)
Impaired healing	1 (1, 1.1%)	--	1 (1, 1.6%)
Device extrusion	1 (1, 1.1%)	--	--
Lead migration	1 (1, 1.1%)	--	1 (1, 1.6%)
Increased low back pain	--	1 (1, 1.1%)	--
Bradycardia	--	--	1 (1, 1.6%)
Radiculopathy	1 (1, 1.1%)	--	--

Uncomfortable stimulation	1 (1, 1.1%)	--	--
Gastroesophageal reflux	1 (1, 1.1%)	--	--
Tendonitis	--	--	1 (1, 1.6%)
Sciatica	--	1 (1, 1.1%)	--
Myalgia	1 (1, 1.1%)	--	--
Arthralgia	1 (1, 1.1%)	--	--

Key: AE – adverse event; CMM – conservative medical management; kHz – kilohertz; n – number; PDN – painful diabetic neuropathy; SCS – spinal cord stimulation.

Source: Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Published online April 05, 2021. doi:10.1001/jamaneurol.2021.0538

Conclusions: Overall, the Senza PDN trial has demonstrated substantial and maintained pain relief and neurological improvement over 12 months, providing clear and high-quality evidence supporting the use of 10 kHz SCS for the treatment of PDN patients with refractory symptoms..

3.1 Quality of Life Outcomes

Safety Profile

Senza SCS has a proven safety profile as demonstrated in clinical trials and has been in commercial use in the United States since 2015 with over 70,000 patients implanted worldwide, to date. For detailed Safety Information, Warnings, Adverse Events, and Precautions, please refer to the Nevro Physician Manual (www.nevro.com/physicianmanuals). The Senza SCS Systems are MRI Conditional, which means that safety has been demonstrated only within specifically defined conditions. Scanning under different conditions may result in severe patient injury or device malfunction. Refer to the Nevro MRI Guidelines (www.nevro.com/physicianmanuals) for detailed information on MRI safety and conditions for MRI scanning of patients implanted with Nevro products. On-label safety information is available at: https://www.nevro.com/English/us/safety/default.aspx

3.2 Economic Outcomes

The management of diabetes significantly raises healthcare costs, as on average, patients with diabetes in the United States incur double the medical expenditures of those without the disease. Additionally, those with diabetes have a higher probability of experiencing days lost from work, disability, and premature mortality. A study from the American Diabetes Association showed that direct medical expenditures from diabetes constituted $24.6 billion, in comparison to $44.1 billion for other general medical conditions. The primary drivers of diabetes costs were inpatient days (43.9%), nursing home care (15.1%), and office visits (10.9%) (Hogan 2002).

3.3 Econometrics

PDN is associated with considerable direct and indirect economic costs and high clinical utility and treatment-discontinuation rates (Kiyani 2020; O'Connor 2009; Pop-Busui 2017; Sadosky 2015; Yang 2015).

A retrospective analysis, using the Humedica Electronic Medical Record (EMR) claims database, was conducted to evaluate the healthcare utilization costs in patients with diabetes (n=288,328) relative to clinical PDN. The authors observed a trend toward increased clinical utility from diabetes-only patients, as well as patients who reported pain (painful diabetic neuropathy) due to diabetic peripheral neuropathy.

Direct medical costs were 4 times higher for patients with PDN vs patients with diabetes alone ($31,211 vs $7,875, respectively) (Sadosky 2015).

- Pain severity in PDN patients was associated with increased costs ($34,592 vs $31,112 for severe PDN [pain score ≥7] vs PDN [pain score ≥1]) and clinical utility. Compared to the PDN cohort, patients with severe PDN had higher rates of emergency department visits (57.0% vs 50.7%) and hospitalizations (62.8% vs 40.2%), respectively (Sadosky 2015).
- A retrospective claims analysis using the MarketScan database found that baseline costs associated with PDN patients were 20% higher than patients with diabetes alone (95% confidence interval [CI] [1.19,1.21], *P*<0.001) (Kiyani 2020).

4.0 CURRENT PAYER COVERAGE

All commercial payers currently cover the use of Senza SCS for the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. Nevro is seeking additional coverage of 10 kHz SCS for the treatment of PDN and NSRBP.

Centers for Medicare and Medicaid Services (CMS) has a NCD (160.7) on Electrical Nerve Stimulators which covers implantable dorsal column stimulators (also known as spinal cord stimulators) as a late or last resort for patients with chronic intractable pain who have tried other treatment modalities but did not achieve satisfactory relief or were judged to be unsuitable or contraindicated for them. This coverage policy includes multiple chronic pain indications, including PDN.

Commercial health plans such as Providence Health Plan, Medica, Centene and others currently have positive coverage decisions for the use of Senza SCS to treat patients managing PDN. Effective March 1, 2022, United Healthcare's SCS policy also covers diabetic neuropathy for high-frequency spinal cord stimulation. These medical policies rely on specific criteria for the use of Senza and at times are approved on a case-by-case basis for patients with PDN. Many of the other major health plans do not currently cover Senza SCS for PDN (Anthem, Cigna, Humana). Their medical policies are missing valuable clinical research that has been recently published from the SENZA-PDN RCT.

APPENDIX A: LITERATURE SEARCH METHODOLOGY

<table>
<tr><th>Citation</th><th>Design/Sample Size/Treatments</th><th>Key Inclusion and Exclusion Criteria</th><th>Endpoints/Results</th></tr>
<tr><td colspan="4">Ongoing Trials</td></tr>
<tr>
<td>Senza-PDN
Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. Diabetes Care. doi: 10.2337/dc21-1813
Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. JAMA Neurol. Published online April 05, 2021. doi:10.1001/jamaneurol.2021.0538
Data on file, Nevro Corp. SENZA-PDN 6-month data [presentation]. 2020d.
Data on file, Nevro Corp. US PDN 6-month clinical study report. 2020e.
Mekhail NA, Argoff CE, Taylor RS, et al. High-frequency spinal cord stimulation at 10 kHz for the treatment of painful diabetic neuropathy: design of a multicenter, randomized controlled trial (SENZA-PDN). Trials. 2020 Jan 15;21(1):87.
Petersen E. Neuromodulation for treatment of painful diabetic neuropathy: a multicenter, randomized, controlled trial. Presented at: American Diabetes Association 80th Scientific Sessions; June 12-16, 2020; Virtual Experience.
ClinicalTrials.gov ID: NCT03228420</td>
<td>Design: prospective, multicenter, open-label, randomized, controlled trial.
Sample size:
n=113 (10 kHz SCS+CMM)
n=103 (CMM alone)
Treatment: Patients with treatment-refractory PDN randomized 1:1 to receive either 10 kHz SCS+CMM or CMM alone. Pre-defined follow-up times were 3, 6, 12, and 24 months, with 3-month evaluation utilized for the primary endpoint. At 6 months, eligible patients were allowed to crossover.</td>
<td>Inclusion:
• Patients ≥22 years of age
• PDN diagnosis with symptoms ≥12 months
• ≥5 cm on a 10 cm VAS
• Stable analgesic regimen
• Refractory to pregabalin or gabapentin and ≥1 additional analgesic therapy class
Exclusion:
• HbA1c >10%
• BMI >45 kg/m²
• Upper limb pain intensity ≥3 cm
• Opioid daily dose >120 mg morphine equivalents</td>
<td><u>Primary</u>
• PP analysis composite outcome of ≥50% pain relief and no worsening in neurologic deficit at 3 months:
o 10 kHz SCS+CMM group: 86% (n=87)
o CMM alone group: 5% (n=93)
o P<0.001
• ITT analysis composite outcome of ≥50% pain relief and no worsening in neurologic deficit at 3 months:
o 10 kHz SCS+CMM group: 78.9% (75 of 95 patients)
o CMM alone group: 5.3% (5 of 94 patients)
o Difference in improvement with no neurologic deficit between groups: 73.6%, P<0.001
<u>Key Secondary</u>
<table>
<tr><th>Outcome</th><th>10 kHz SCS+CMM (n=88)[a]</th><th>CMM alone (n=96)[a]</th><th>P-value</th></tr>
<tr><td>Lower limb pain VAS ≤3 cm at 3 months, n//N (%)</td><td>69/88 (78.4%)</td><td>5/96 (5.3%)</td><td><0.001[b]</td></tr>
<tr><td>Patients crossing over at 6 months, n/N (%)</td><td>0/87 (0.0%)</td><td>76/93 (81.7%)</td><td><0.001[b]</td></tr>
<tr><td>Lower limb pain relief ≥50% at 6 months, n/N (%)</td><td>74/87 (85.1%)</td><td>5/93 (5.4%)</td><td><0.001[b]</td></tr>
<tr><td>Remitters at 6 months, n/N (%)</td><td>53/88 (60.2%)</td><td>1/95 (1.1%)</td><td><0.001[b]</td></tr>
<tr><td>Overall improvement in neurological assessment
at 3 months, n/N (%)
at 6 months, n/N (%)</td><td>
63/87 (72.4%)
52/84 (61.9%)</td><td>
6/94 (6.4%)
2/92 (3.3%)</td><td>
<0.001[b]
<0.001[b]</td></tr>
<tr><td>Changes in HRQoL at 6 months
EQ-5D-5L index, mean (SD)
EQ-5D-5L health VAS, mean (SD)</td><td>
0.130 (0.159)
15.9 (21.6)</td><td>
-0.031 (0.127)
-1.7 (23.0)</td><td>
<0.001[e]
<0.001[e]</td></tr>
<tr><td>Percentage change in HbA1c at 6 months, mean (SD)</td><td>1.5% (14.9%)</td><td>2.6% (15.4%)</td><td>0.649[e]</td></tr>
</table>
</td>
</tr>
</table>

Other Endpoints at 3 and 6 months

- 6-Minute wa k test average distance increase
  - 10 kHz SCS+CMM, baseline: 287.5 m
  - 10 kHz SCS+CMM, 3 months: 336.4 m (17% increase)
  - CMM alone, baseline: 293.4 m
  - CMM, 3 months: 296.2 m (0.9% increase)
- Reduction in pain-related sleep disturbance
  - 10 kHz SCS+CMM, 6 months: 61.9% reduction (improvement in sleep quality)
  - CMM, 6 months: −5.3% reduction (worsening in sleep quality)
- Opioid utilization, 6 months
  - Decrease in utilization compared to baseline
    - 10 kHz SCS+CMM: 23% (10/43) patients
    - CMM: 8% (3/38) patients
  - Increase in utilization compared to baseline
    - 10 kHz SCS+CMM: 2% (1/43) patients
    - CMM: 11% (4/38) patients
- Hospital and ED visits number of visits, 6 months
  - 10 kHz SCS+CMM: 1.27 visits (7 fewer visits per 100 patients)
  - CMM: 1.35 visits

Safety

- A total of 18 study-related AEs was reported for the 10 kHz SCS+CMM group
- Infections/wound dehiscence requiring device removal occurred in 2 patients in the 10 kHz SCS+CMM group (2/90, 2.2%)
- No study-related AEs were reported in the CMM alone group, as the protocol did not require any specific CMM treatments

AE	10 kHz SCS + CMM (n=87)
Total study-related AEs, n (# of patients, %)	18 (14, 12.4%)
Rate as serious AEs	2 (2, 1.8%)
Study-related AEs by type	-
Infection	3 (3, 2.7%)
Wound dehiscence	2 (2, 1.8%)
Impaired healing	1 (1, 0.9%)
Device extrusion	1 (1, 0.9%)
Incision site pain	1 (1, 0.9%)
IPG site discomfort	1 (1, 0.9%)
Lead migration	1 (1, 0.9%)

			Contact dermatitis: 1 (1, 0.9%) Urticaria: 1 (1, 0.9%) Radiculopathy: 1 (1, 0.9%) Uncomfortable stimulation: 1 (1, 0.9%) Gastroesophageal reflux: 1 (1, 0.9%) Myalgia: 1 (1, 0.9%) Arthralgia: 1 (1, 0.9%) Hyporeflexia: 1 (1, 0.9%)
SENZA-NSRBP Kapural, L. Jameson, J, Johnson, C et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. Journal of Neurosurgery: Spine (2022). https://doi.org/10.3171/2021.12.SPINE211301	**Design:** prospective, multicenter, open-label, randomized, controlled trial. **Sample size:** n=83 (10 kHz SCS+CMM) n=76 (CMM alone) **Treatment:** Patients with chronic back pain that is refractory to conventional medical management (CMM) and who have no history of spine surgery and are not acceptable candidates for spine surgery randomized 1:1 to receive either 10 kHz SCS+CMM or CMM alone. Pre-defined follow-up times were 3, 6, 12, and 24 months, with 3-month evaluation utilized for the	**Inclusion Criteria:** • Have been diagnosed with chronic, intractable pain of the trunk and/or limbs (VAS ≥ 5) which has been refractory to conservative therapy for a minimum of 3 months. • Be an appropriate candidate for the surgical procedures required in this study based on the clinical judgment of the implanting physician • Patients ≥18 years of age	**Primary Endpoints** Responder rate (≥ 50% pain relief) • 3 Month: 1.3% CMM alone, 80.9% 10 kHz SCS+CMM • 6 Month: 2.7% CMM only, 80.0% 10 kHz SCS+CMM **Secondary endpoints evaluated 3 and 6 months postbaseline for both randomized arms and crossovers** (6M Data is represented below) ODI responder: 3/75 (4%); 51/65 (78.5%); <0.001 Mean % change in VAS pain score-back (SD): 6.2 (21.7); -72 (32); <0.001 PGIC improvement (better or a great deal better), n (%): 1/75 (1.3%); 46/65 (70.8); <0.001 Mean change in EQ-5D-5L score (SD): -0.042 (0.144); 0.201 (0.126); <0.001 Mean change in daily opioid dose, MME (SD): 1.0 (10.8); -17.7 (27.0); <0.001 **Safety Outcomes (12M)** **Safety Population* (N=145)**: Number of Subjects with AE (% of Population) Total AE n=41: 35 (24.1%) **Most Common Adverse Event Description** Implant site pain: 7 (4.8%) Implant site infection: 5 (3.4%) Transient CSF leakage: 3 (2.0%)

	primary endpoint. At 6 months, eligible patients were allowed to crossover.		*Safety population is all patients who underwent a device procedure (trial and/or implant)
Post Hoc Analyses			
Senza-PPN Galan V, Scowcroft J, Chang P, et al. 10-kHz spinal cord stimulation treatment for painful diabetic neuropathy: results from post-hoc analysis of the SENZA-PPN study. *Pain Manag.* 2020;10(5):291-300.	**Design:** Post-hoc analysis of subset of patients with PDN enrolled in a prospective, single-arm, multicenter early feasibility study of 10 kHz SCS treatment in patients with PPN. **Sample size:** N=9 (PDN subset), 8 patients received a permanent device, 7 patients completed 12-month follow-up **Treatment:** Patients received 2 epidural leads spanning T8–T11 vertebra and underwent SCS therapy trial (1 week). Patients who experienced ≥40% pain relief received 10 kHz SCS permanent implantation, Stimulation amplitude and various programming options were customized to each patient to	**Inclusion:** • Clinical diagnosis of PDN of lower limbs • Pain refractory to CMM ≥3 months • Stable analgesic regimen • Lower/upper limb VAS pain score ≥5 cm **Exclusion:** • Mononeuropathy diagnosis of the trunk • Previous SCS failure for chronic intractable pain	**Pain outcomes** • Mean VAS pain scores o Baseline: 8.0±1.2 cm o 6 months: 2.0±1.2 cm ▪ 87.5% (7/8) both responders (≥50% pain relief) and remitters (VAS ≤3.0) o 12 months: 2.1 ± 2.3 cm • SF-MPQ-2 scores (total pain) o Baseline: 5.1 o 3 months: 1.8 (3.3-point decrease from baseline) o 12 months: 2.2 (2.9-point decrease from baseline) o Decreases were observed in all 4 domains (continuous pain, intermittent pain, neuropathic pain, and affective descriptors of pain) at 3 and 12 months **Humanistic outcomes** • Functioning, disability, sleep o PDI mean scores (measure of pain interference with daily function) decreased from baseline ▪ Baseline: 37.6 ▪ 6 months: 15.4 ▪ 12 months: 27.1 o GAF mean scores (measure of ability to function) increased from baseline ▪ Baseline: 73.9 ▪ 6 months: 88.6 ▪ 12 months: 88.1 o PSQ-3 composite mean scores (measure of pain-related sleep disturbance) decreased ≥50% ▪ Baseline: 21.7 ▪ 6 months: 6.0 ▪ 12 months: 10.9 • Perception of effectiveness: o Patient-reported global impression of change ▪ 3 months: 100% of patients rated pain as "better" ▪ 12 months: 100% of patients rated pain as "better" o Clinician-reported global impression of change ▪ 3 months: 88.9% of patients at least "moderately better"

<table>
<tr><td></td><td>maximize pain relief.</td><td></td><td>▪ 12 months: 81.3% of patients “moderately better”
<u>Safety</u>
• Neurologic assessments: At 3 and 12 months, neurologic assessments demonstrated improvement or maintenance in comparison with baseline scores. No patients showed evidence of neurological functioning in any domain. All improvements observed were in sensory and reflex assessments (not motor).
• AEs: A total of 8 nonserious AEs were experienced by 3 patients. Two of the AEs were deemed study-related (pain in extremity and seroma). Three SAEs were reported, 1 of which was study-related (implant site dehiscence). One patient died of hepatic failure which was unrelated to the 10 kHz SCS device or procedure.</td></tr>
<tr><td colspan="4">Case Series</td></tr>
<tr><td>Sills S. Treatment of painful polyneuropathies of diabetic and other origins with 10 kHz SCS: a case series. Postgrad Med. 2020 May;132(4):352-357.</td><td>Design: Case series
Sample size: N=6, 3 patients with PDN
Treatment: Patients with painful polyneuropathies of diabetes and other origins received 2 epidural octopolar leads implanted spanning T8–T11 vertebra and underwent SCS therapy trial (1 week). Patients who experienced ≥50% pain relief were eligible for 10 kHz SCS permanent implantation with PG placed in the subcutaneous tissue in the flank or buttocks.</td><td>Inclusion:
• Peripheral polyneuropathy
• Refractory to treatment
Exclusion:
• Patients inelig ble to receive SCS implantation</td><td><u>Pain Scores and Pain medication Adjustments</u>
• 3 out of the 6 patients were diagnosed with PDN. No AEs were reported
<table>
<tr><th>Patient number</th><th>Follow-up time (mo)</th><th>VNRS score</th><th>Medications</th><th>Humanistic outcomes</th></tr>
<tr><td>1</td><td>36</td><td>Baseline: 8
Final follow-up: 1</td><td>Baseline: Methadone, Neurontin, Lyrica
Final follow-up: None</td><td>Reported 99% improvement in QoL able to wa k/run ≥6 hours compared with 15 minutes before 10 kHz SCS device. Got off of disability and went back to work</td></tr>
<tr><td>5</td><td>26</td><td>Baseline: 8
Final follow-up: 4.5</td><td>Baseline: Norco, Lyrica
Final follow-up: No change</td><td>Reported overall improvement (by 50% in walking tolerance, by 60% in feet sensation). Reported she could now mow the lawn</td></tr>
<tr><td>6</td><td>38</td><td>Baseline: 7
Final follow-up: 0.5</td><td>Baseline: Opiates
Final follow-up: None</td><td>Reported improvement in function (walk, dance) and able to walk with no limitations in comparison to 100 yards prior to 10 kHz SCS device. Patient able to feel debridement for ulcers whereas before treatment he had no feeling</td></tr>
</table></td></tr>
<tr><td colspan="4">Pivotal Trial for Approved Use</td></tr>
<tr><td>Senza-RCT
Kapural L, Yu C, Doust MW et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back</td><td>Design: Multicenter, randomized, controlled, noninferiority</td><td>Inclusion:
• Chronic intractable pain of the trunk and/or limbs</td><td><u>Primary</u>
• ITT analysis composite outcome of ≥50% back pain relief and no worsening in neurologic deficit at 3 months. No patients in either arm experienced neurologic deficit.
○ 10 kHz SCS: 84.5% of patients</td></tr>
</table>

and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. *Neurosurgery*. 2016 Nov;79(5):667-677. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT. *Anesthesiology*. 2015 Oct;123(4):851-860. ClinicalTrials.gov Identifier: NCT01609972	pivotal trial **Sample size:** n=101 (10 kHz SCS) n=97 (traditional SCS) **Treatment:** Patients with chronic intractable leg and back pain were randomized in a 1:1 to receive stimulation with either 10 kHz SCS or traditional SCS (Precision Plus system).	• Refractory to CMM for ≥3 months • Mean back pain intensity ≥5 cm on the VAS • Mean leg pain intensity ≥5 cm on the VAS • Oswestry Disability Index score of 41 to 80 (out of 100) **Exclusion:** • Active disruptive psychological or psychiatric disorder that would interfere with perception of pain	○ Traditional: 43.8% of patients ○ RR 1.9; 95% CI: 1.4, 2.5; *P*<0.001 (for both noninferiority and superiority) **Secondary** • Percentage of responders (≥50% pain reduction) for leg pain ○ 10 kHz SCS, 24 months: 72.9% of patients ○ Traditional, 24 months: 49.3% of patients ○ Difference in improvement between groups 23.6% (95% CI: 5.9, 38.6; *P*<0.001 [noninferiority]; *P*<0.003 [superiority]) • Percentage of responders (≥50% pain reduction) for back pain ○ 10 kHz SCS, 24 months: 76.5% of patients ○ Traditional, 24 months: 49.3% of patients ○ Difference in improvement between groups 27.2% (95% CI: 10.1, 41.8; *P*<0.001 [for both noninferiority and superiority]) **Safety** • At 24 months, there were few study-related SAEs (5.0% for 10 kHz SCS, 7.2% for traditional SCS, *P*=0.56). No stimulation-related SAEs or neurological deficits occurred in either group. The most common AEs were implant site pain (12.9% in 10 kHz SCS, 13.4% in traditional SCS, *P*=0.91) and uncomfortable paresthesias (0.0% in 10 kHz SCS, 11.3% in traditional SCS, *P*<0.001). Lead migration requiring surgical revision occurred in 3.0% of 10 kHz SCS patients and 5.2% of traditional SCS patients (*P*=0.49).

[a] The N for each assessment may vary due to missing data.

[b] By Fisher's exact test, 2-sided.

[c] Remission was defined as pain VAS score ≤3 cm for 6 consecutive months.

[d] Overall improvement on neurological assessment was defined as no deficit compared to baseline in any motor, sensory, or reflex outcomes and improvement in at least one outcome. Measured by monofilament and pinprick tests.

[e] By Student's *t*-test, 2-sided.

Key: AE – adverse event; BMI – body mass index; cm – centimeter; CI – confidence interval; CMM – conservative medical management; ED – emergency department; GAF – Global Assessment of Functioning; HbA1c – hemoglobin A1c; HRQoL – health-related quality of life; IPG – implantable pulse generator; ITT – intention-to-treat; kg – kilogram; kHz – kilohertz; m – meters; m^2 – meter squared; µs – microsecond; mg – milligram; mNSS – modified Neuropathy Symptom Score; mo – month; n – number; PDI – Pain Disability Index; PDN – painful diabetic neuropathy; PG – pulse generator; PP – per-protocol; PPN – painful polyneuropathy; PSQ-3 – Pain and Sleep questionnaire; QoL – quality of life; RCT – randomized controlled trial; RR – relative risk; SAE – serious adverse event; SCS – spinal cord stimulation; SD – standard deviation; SF-MPQ-2 – short-form McGill pain questionnaire; VAS – visual analog scale; VNRS – verbal numerical rating scale.

APPENDIX B: REFERENCES

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APPENDIX C: ABBREVIATIONS USED WITHIN THE DOSSIER

AAFP – American Academy of Family Physicians
ADA – American Diabetes Association
AE – adverse event
Akt – protein kinase B
BMI – body mass index
CI – confidence interval
CMM – conservative medical management
DN – diabetic neuropathy
DN4 – Douleur Neuropathique
DNA – deoxyribonucleic acid
DSPN – distal symmetric polyneuropathy
ER – endoplasmic reticulum
FAS – full analysis set
FFA – free fatty acids
FDA – Food and Drug Administration
GABA – Gamma aminobutyric acid
GAF – Global Assessment of Functioning
HbA1c – hemoglobin A1c
HDL – high-density lipoprotein
HF – high frequency
HIPAA – Health Insurance Portability and Accountability Act
HRQoL – health-related quality of life
Hz – hertz
IPG – implantable pulse generator
ITT – intention-to-treat
IV – intravenous
kHz – kilohertz
LDL – low-density lipoprotein
mNSS – modified Neuropathy Symptom Score
MRI – magnetic resonance imaging
NSAID – non-steroidal anti-inflammatory drug
OR – operating room
PDI – Pain Disability Index
PDN – painful diabetic neuropathy
PDUFA – Prescription Drug User Fee Act
PG – pulse generator
PI3-K – phosphatidylinositol-3 kinase
PN – peripheral neuropathy
PP – per-protocol
PPN – painful polyneuropathy
PSQ-3 – Pain and Sleep Questionnaire
QoL – quality of life
RCT – randomized controlled trial
RNS – reactive nitrogen species
ROS – reactive oxygen species
RR – relative risk
SAE – serious adverse event
sBLA – supplemental Biologics License Application
SCS – spinal cord stimulation
SD – standard deviation
SF-36 – Short-Form 36-Item Survey
SF-MPQ-2 - short-form McGill Pain Questionnaire
sNDA – supplemental New Drug Application
SNRI – serotonin-norepinephrine reuptake inhibitor
TCA – tricyclic antidepressant
US – United States
VAS – visual analog scale
VNRS – verbal numerical rating scale
WDR – wide dynamic range

ADDENDUM

PAYER POLICY Analog – *(Actual payer's name has been redacted/ replaced with "PAYER")*

Spinal Cord Stimulation of the Dorsal Column for Treatment of Pain *PAYER* Policy No. III-DEV.23

UTILIZATION MANAGEMENT POLICY TITLE: SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION FOR TREATMENT OF PAIN EFFECTIVE DATE: November 16, 2020

This policy was developed with input from specialists in neurology and physical/rehabilitative medicine and endorsed by the PAYER Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all PAYER plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to PAYER re and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact *PAYER* Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically.

Providers with questions about this *PAYER's* utilization management policy may call the *PAYER* Provider Service Center toll-free at 1-800-xxx-xxxx. *PAYER* utilization management policies are not *PAYER* advice. Members should consult with appropriate health care providers to obtain needed *PAYER* advice, care and treatment.

PURPOSE To promote consistency between Utilization Management reviewers by providing the criteria that determine *PAYER* necessity.

BACKGROUND Definitions

A. Complex regional pain syndrome (CRPS), (also known as reflex sympathetic dystrophy, algoneurodystrophy/algodystrophy, causalgia syndrome) is a form of chronic pain usually affecting an arm or leg and normally developing after an injury, surgery, infection, stroke, or heart attack. This presentation is known as CRPS Type I. CRPS can also arise from direct injury to a nerve, and is known as CRPS Type 2. In CRPS, the pain intensity is out of proportion to the severity of the initial incident, and its cause is not clearly understood. Symptoms vary, with pain, swelling, redness, and noticeable changes in temperature and hypersensitivity (e.g., to cold and touch) usually occurring first. Over time, the limb may become cold and pale and undergo skin and nail changes, as well as developing muscle spasms and tightening.
B. A dorsal root ganglion (DRG) is a cluster of nerve cell bodies in the posterior roots of spinal nerves that extend outward beyond the vertebrae. Pain signals coming from the lower limbs pass through the DRG to the spinal cord and subsequently to the brain.
C. Failed back surgery syndrome (FBSS), also known as post laminectomy syndrome, is characterized by persistent back and/or leg pain following otherwise successful back surgery, frequently following a laminectomy. Following spine surgery, major pain relief is expected, but rarely is there total pain relief. A fraction of post-surgical pain is normal. However, the term FBSS is reserved for individuals who continue to suffer from a majority of their pain symptoms following surgery.
D. Neuropathic pain originates and is perpetuated within the nervous system itself, without ongoing stimulation from an injury. Pain may arise from a primary lesion or from other dysfunction or disease affecting the nervous system. Prevalence of neuropathic pain is estimated to affect approximately eight percent of the population. Neuropathic pain may often respond poorly to standard therapies, can last indefinitely, and can increase in severity over time, often leading to severe disability with markedly reduced quality of life. Examples of neuropathic pain include, but are not limited to, complex regional pain syndrome (CRPS), diabetic neuropathy/polyneuropathy, failed back syndrome (FBS), phantom limb pain, postherpetic neuralgia, post-stroke pain, or trigeminal neuralgia.
E. Peripheral neuropathy/polyneuropathy is a problem with the functioning of the nerves outside the spinal cord. Symptoms of peripheral neuropathy may include numbness, weakness, burning pain (especially at night), and loss of reflexes. Polyneuropathy is the most common form of peripheral neuropathy, and may advance to compromise swallowing, breathing, or eye movements. Diabetic peripheral neuropathy is a type of nerve damage that occurs when prolonged high blood sugar levels cause permanent injury to nerve fibers, most often affecting nerves in the legs and feet.
F. Spinal cord stimulation utilizes low-voltage electrical impulses to stimulate large spinal nerve fibers, which act to block small nerve fiber responses that would otherwise be interpreted as pain. Electrodes are placed in the epidural space within the spinal column. The dorsal root ganglion is a bundle of sensory nerves located within

the epidural space. Stimulation of the dorsal root produces focused therapy to the focal area affected by these nerve bundles. The intended outcome is suppression of pain in individuals experiencing severe chronic pain refractory to standard therapy. Implantation of the stimulation device is done in two phases:

1. Phase one is a trial using temporary electrical stimulation. Either percutaneous or surgical implantation of the leads, with an external trailing neurostimulator (aka, pulse generator), can be used for the screening test. The trial is usually performed from 3 to 7 days.
2. Phase two consists of permanent implantation of both the leads and the neurostimulator. If the individual experiences a positive response in symptoms, permanent implantation may result. The neurostimulator is inserted under the skin through a small incision in the upper buttock, and the permanent lead is implanted in the epidural space. Implantation is typically done as an outpatient procedure. G. Spinal cord stimulation system (aka, dorsal column stimulation system) is composed of the following components:
    a) Neurostimulator – a device similar to a pacemaker, which sends electrical pulses to the spine. It is surgically implanted under the skin in the abdomen or upper buttock. Standard spinal cord stimulation applies tonic stimulation to the spinal cord (i.e., regularly spaced, mild electrical pulses [e.g., 1-kHz] of energy), and the individual experiences a tingling sensation (paresthesia) intended to interrupt the transmission of pain signals to the brain. Modifications used to stimulate the spinal cord include, but are not limited to:
        1) High-frequency stimulation (Senza Spinal Cord Stimulation System), which uses higher frequency pulses (e.g., 10-kHz) to interrupt the pain pathway while markedly reducing or eliminating paresthesia.
        2) Burst stimulation, which uses low-energy closely-spaced, but intermittent, pulses of energy with the intent of producing little-to-no paresthesia.
        3) Position-adaptive stimulation, which is designed to automatically adapt stimulation amplitude in response to changes in an individual's position or activity.
        4) Multicolumn-based stimulation, which applies multiple leads to various spinal cord column locations, with the intent of applying stimulation and paresthesia to a broader area of the spine.
    b) Leads - insulated *PAYER* wires that deliver neurostimulation to the epidural space near the spine
    c) Physician programmer - a computer allowing the clinician to adjust the neurostimulation system and set stimulation levels
    d) Handheld programmer - a device similar to a remote control that can be used by the individual to adjust pain relief based on changing pain levels throughout the day (e.g., with changing degrees of activity). H. Standard therapies used for neuropathic pain include, but are not limited to:
        1) Back surgery
        2) Neurosurgery
        3) Percutaneous neurostimulation therapies (e.g., transcutaneous electrical nerve stimulation [TENS], motor cortex stimulation)
        4) Pharmacotherapy (e.g., antidepressants, anticonvulsants, opioids, botulinum toxin)
        5) Physical therapy (e.g., acupuncture, spinal manipulation)
        6) Psychotherapy or cognitive behavioral therapy (e.g., biofeedback, relaxation techniques).

BENEFIT CONSIDERATIONS

1. Prior authorization is required for both spinal cord stimulation trial and permanent implantation, including reoperation. Please see the prior authorization list for product specific prior authorization requirements.

2. Prior authorization is not required for removal without intended reoperation/implantation.

3. Coverage may vary according to the terms of the member's plan document.

4. Spinal cord stimulation of the dorsal column for treatment of intractable pain is investigative and therefore not covered for all other indications not addressed in this policy, including but not limited to: angina pectoris/myocardial ischemia, arachnoiditis, cancer associated pain, chronic visceral abdominal pain, cluster/migraine headache, intercostal neuralgia, lower limb ischemia, (chronic/critical), non-diabetic peripheral neuropathy, phantom limb syndrome, post herpetic neuralgia, post-cervical spine surgery, and spinal cord injury.

5. Dorsal root ganglion stimulation for the treatment of pain is investigative and therefore not covered.

6. If the *PAYER* Necessity Criteria and Benefit Considerations are met, *PAYER* will authorize benefits within the limits in the member's plan document.

7. If it appears that the *PAYER* Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the *PAYER* director or an external reviewer. Practitioners are reminded of the appeals process in their *PAYER* Provider Administrative Manual.

***PAYER* NECESSITY CRITERIA NOTE:**

Prior authorization is required for spinal cord stimulation trial and permanent implantation, including reoperation.

I. Indications for trial spinal cord stimulation: Documentation in the *PAYER* records indicates that all of the following criteria have been met:

A. Spinal cord stimulator system has received final FDA approval. Examples of FDA approved device systems include, but are not limited to:

1. Eon® Neurostimulation Systems (St. Jude Medical)

2. Precision™ Spinal Cord Stimulation Systems, now marketed as Precision Plus SCS System (Boston Scientific)

3. Protégé™ System (St. Jude Medical)

4. Restore™ Systems (Medtronic)

5. Senza Spinal Cord Stimulation System (Nevro Corp.)

B. Individual has a diagnosis of one of the following chronic neuropathic pain conditions of the trunk or limbs:

1. Complex regional pain syndrome (also known as reflex sympathetic dystrophy, algoneurodystrophy/algodystrophy, causalgia syndrome)

2. Failed back surgery syndrome (FBSS)

3. Moderate to severe diabetic peripheral neuropathy, when all of the following criteria have been met:

a) Pain scale intensity rating of 50% or higher using a standard pain relief inventory assessment tool (e.g., Visual Analog Scale, Numeric Rating Scale, Verbal Rating Scale) b. Neuropathic pain refractory to a minimum of 12 months of conservative therapy, including all of the following therapies:

1) Non-steroidal anti-inflammatory drug [NSAIDS]

2) Antidepressant

3) Anticonvulsant

C. Documentation of all of the following:

1. Intractable pain for a minimum of twelve months duration

2. Failure of standard therapy (i.e., conservative management, standard surgical intervention) or unsuitability of standard therapies

3. Comprehensive physical examination, including a pain evaluation.

D. Psychiatric/psychological evaluation has been conducted, and all of the following apply:

1. Evaluation has been completed within the past 12 months

2. Continued optimal management of any previously diagnosed (greater than 12 months) mental or neurobehavioral condition(s)

E. None of the following are present:

1. Coagulation disorder (e.g., coagulopathy, severe thrombocytopenia)

2. Current or chronic infection

3. Implanted cardiac pacemaker or defibrillator

4. Malignancy-derived pain

5. Vascular claudication

II. Indications for permanent spinal cord implantation: Documentation in the *PAYER* records indicates that all of the following criteria have been met:

A. *PAYER* necessity criteria is consistent with I.A .- E., above.

B. Individual has completed a trial using either percutaneous leads or surgically implanted leads with documentation of all of the following:

1. Trial duration of a minimum of three days

2. Greater than or equal to 50% reduction in pain using a standard pain relief inventory assessment tool (e.g., Visual Analog Scale, Numeric Rating Scale, Verbal Rating Scale)

III. Indications for reoperation: Documentation in the *PAYER* record indicates one of the following:

A. Development of fibrosis surrounding the electrode tip

B. Electrode misalignment or migration has occurred

C. Infection necessitating removal of the stimulation system

D. Spinal cord stimulator and/or the battery are no longer operational

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) • For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp?

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83. Levy RM, Mekhail N, Kramer J., et al. Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. J Pain. 2019;S1526- 5900(18)30681-3. doi: 10.1016/j.jpain.2019.08.005.

84. van Bussel CM, Stronks DL, Huygen FJPM. Dorsal Column Stimulation vs. Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Confined to the Knee: Patients' Preference Following the Trial Period. Pain Pract. 2018;18(1):87-93. doi: 10.1111/papr.12573.

85. Van Buyten JP, Smet I, Liem L, Russo M, Huygen F. Stimulation of Dorsal Root Ganglia for the Management of Complex Regional Pain Syndrome: A Prospective Case Series. Pain Pract. 2015;15(3):208-16. doi: 10.1111/papr.12170. 09/2020 MPC: No new references

Hamann, Valerie (HCA)

From: Karen James [redacted]
Sent: Monday, September 12, 2022 1:12 PM
To: HCA ST Health Tech Assessment Prog
Cc: Allison Waxler
Subject: Comments on Spinal Cord Stimulators
Attachments: NASS Spinal Cord Stimulation Coverage Recommendation.pdf

External Email

Good afternoon,

NASS supports coverage for spinal neurostimulators as outlined in the attached coverage recommendation. Thank you and please let me know if there are any questions, Karen

Karen James
Senior Manager of Health Policy
North American Spine Society
[redacted]
www.spine.org

Hamann, Valerie (HCA)

From: Chan, Wendy [CA999] [redacted]
Sent: Wednesday, August 31, 2022 3:30 PM
To: HCA ST Health Tech Assessment Prog
Subject: Comment to support 2022 Topic Assessment for Spinal Cord Stimulation
Attachments: UC202305100 EN SCS WA State HTA SCS Comments FY23.pdf

External Email

Dear Director Birch,

Thanks for the opportunity to comment. Please see attached support for reconsideration/re-assessment of SCS for the 2022 HTA Topic agenda.

Please let me know if you have questions or need additional items to best support.

Best, Wendy

Wendy Chan, MHA
Vice President, Health Economics, Policy and Reimbursement

Medtronic
Neuromodulation, Pelvic Health, & Neurovascular

[redacted]
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Engineering the extraordinary

Medtronic

August 30, 2022

Via online submission at: shtap@hca.wa.gov

RE: State of WA Health Care Authority- 2022 HTA Topic Assessment: Spinal Cord Stimulation (SCS)

Dear Director Birch,

We are writing to provide support for the re-review of spinal cord stimulation (SCS) based on the latest body of clinical evidence confirming this as an appropriate therapy for patients with chronic intractable pain of the trunk and/or limbs. We support local efforts by physicians, the respective professional societies, and patients to bring this technology for re-assessment since the topic was last reviewed by the Health Technology Clinical Committee (HTCC) in 2010. We appreciate the reconsideration for review.

Medtronic is a global medical technology and services company which offers a variety of products and therapies to serve our patients, including FDA-approved therapies such as spinal cord stimulation (SCS) for the treatment of chronic, intractable pain. SCS is a technology implanted under the skin to deliver mild electrical pulses to the spine, modifying pain messages before they reach the brain, and has proven to provide long-term effective pain relief and improve quality of life. It is also important to note that spinal cord stimulation has been around for decades and is a well proven and accepted treatment for specific conditions and patient populations. Furthermore, SCS is often a last resort for many injured workers. It has long-standing coverage through the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD 160.7), multiple commercial payers, and other state workers' compensation and Medicaid plans.

SCS continues to be a safe treatment option afforded to patients who suffer from chronic intractable pain. The technology continues to advance in response to better targeting areas of pain with advanced waveforms and expansion of indications based on rigorous regulatory approval and supporting clinical evidence. Earlier this year, Medtronic received FDA approval for SCS for the expanded indication to support painful diabetic peripheral neuropathy (DPN) of the lower extremities. Two independent randomized controlled trials (de Vos et al. and Slangen et al.) – one of a Medtronic device and one of a competing similar product - show patients with chronic DPN, with moderate to severe symptoms and refractory to other treatments, achieve significant pain relief when treated with SCS with conventional medical management (CMM) compared to CMM treatments alone.[1,2]

[1] de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. *Pain.* 2014;155(11):2426-243

[2] Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. *Diabetes care.* 2014;37(11):3016-302

SCS is a technology implanted under the skin to deliver mild electrical pulses to the spine, modifying pain messages before they reach the brain, and has proven to provide long-term effective pain relief and improve quality of life.[3,4] Approximately 9.5 million Americans are misusing opioids with 65 percent doing so to relieve physical pain.[5] Further, an estimated 25 percent of chronic pain patients are misusing prescription oral opioids.[6] While SCS does not treat opioid addiction, it provides patients a way to manage their chronic pain as an alternative or adjunct to oral opioids when conventional therapies and medications, including oral opioids, provide inadequate pain relief or intolerable side effects.

Recommendation

We support the re-review of SCS and appreciate the WA Health Care Authority prioritizing the topic for review in its 2022 topic assessment. We believe that the local clinical community will facilitate support for this review and help advocate the need of SCS for the state-managed health plans based on additional evidence. We look forward to providing input to the review process.

If you have questions, feel free to reach out to me at [redacted] or Christine Ricker (Director, HEPR) at [redacted]

Sincerely,

Wendy Chan

Wendy Chan
Vice President, Health Economics Policy Reimbursement (HEPR)
Neurosciences

[3] 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;63(4):762-770; discussion 770.

[4] Harke H, Gretenkort P, Ladleif HU, Rahman S. Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. Eur J Pain. 2005:9(4);363-373.

[5] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.
https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf. Accessed April 2022.

[6] Vowles KE, McEntee ML, Julnes PS, et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain. 2015;156(4):569-576.

Table 5. Responses to Public Comments on the Key Question Posting.

	Comments	Commenter(s)	Response
1	The following individuals provided experiences of living with pain treated by SCS systems, the costs from a patient's perspective, or otherwise hoping to one day gain access.	Individual David T. Pitkethly	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
2	The following individuals provided experiences with SCS systems from a clinician's perspective.	Individuals John Hatheway Emilie Jones John Loeser Patrick Soto	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
3	The following individual made specific requests to the Washington State Healthcare Authority urging them to cover SCS.	Individual David T. Pitkethly	Comments pertaining to formulation of policy do not require a response by the evidence vendor. The vendor does not suggest, recommend, determine, or evaluate coverage policy. These are referred to the HTAP.
4	The following device manufacturer or associations expressed appreciation for the consideration of a re-review.	Device manufacturer Wendy Chan* Associations and societies Farshad Ahadian† (Sharon Kneebone)	Thank you for the comments.
5	The following device manufacturer agreed with the proposed Key Questions.	Device manufacturer Wendy Chan*	Thank you for the comments.
6	Regarding the PICOTS Scope, we would suggest clarifying what trial study designs would meet the "Comparators" definition of "medical and/or surgical treatment (appropriate to condition)". The most common comparator in SCS randomized clinical trials is "conservative medical management" (CMM), which includes a broad array of interventions tried and failed before SCS, including but not limited to: medication management (opioid and non-opioid), epidural steroid injections, radiofrequency ablation, physical therapy, and chiropractic care. We would like to confirm that these forms of CMM as a comparator to SCS would be included in the PICOT inclusion criteria under "medical treatment".	Device manufacturer Wendy Chan*	If RCTs or prospective, low risk of bias studies that control for confounding comparing SCS with any of the CMM strategies listed (individually or collectively) would be included if other inclusion criteria are met.

7	Suggestion that the PICOTs include RCTs which compare different types/modalities of SCS.	Device manufacturer Wendy Chan[*] Associations and societies Keri Kramer[‡]	These comments were discussed with the HTAP during topic refinement. Comparison of different SCS modes of operation, waveforms or frequencies was not part of the final review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS.
8	Concern over publications which meet PICOTS, and included editorials that point out flaws in those studies, specifically Hara 2022.	Device manufacturer Wendy Chan[*] Associations and societies Keri Kramer[‡]	Commentaries, editorials, and similar publications are not part of the PICOTS inclusion criteria for the review. In general, it has been observed that there are a variety of criticisms of studies that present differing perspectives on the evidence in any given study or review as do author responses to such criticisms (e.g., reply by Gulati, et. al, JAMA March 14, 2023 Volume 329, Number 10). All studies have strengths and limitations. This update review focuses on evidence presented in studies meeting inclusion criteria. All studies listed met the inclusion criteria set a priori. Consultation with clinical experts for this review indicated that it is unclear how comparable or applicable the parameters used in the RCTs are to usual clinical practice and that there is likely substantial heterogeneity in what is used clinically, and SCS delivery parameters are tailored to the patient.

			All included studies had some potential for bias and technical factors that may limit their applicability to other populations. One trial (Al-Kaisy) used a trial-specific program for stimulation that limits its applicability to broader clinical use for example.
9	The draft PICOTS Scope presented in Table 1 of the call for public comment by the Washington State Health Care Authority would exclude recent randomized controlled trial (RCT) evidence on the use of SCS. Historical RCTs of SCS have compared SCS to conventional medical management (CMM; first- and second-line treatments detailed above), which was the standard of care at the time of the studies. Once superiority of SCS was observed versus CMM and SCS approvals were obtained for an indication (e.g., persistent spinal pain syndrome type [PSPS-T2], previously referred to as failed back surgery syndrome [FBSS]), the new standard of care became the SCS available at the time of approval. Trials of new stimulation paradigms have therefore used open-loop / fixed-output, low-frequency SCS as the comparator arm. This comparative trial evidence, some of which is up to 24- month follow-up, should not be disregarded.	<u>Device manufacturer</u> Todd Davis[§]	Based on our preliminary and final searches, a number of new studies included in the review compared SCS with CMM. All Comments related to comparison of different SCS types or modes of operation were discussed with the HTAP during topic refinement. The program's preference was to keep the scope of the update consistent with that of the prior report
10	SCS compared to CMM may not be useful in patients that have already failed other treatment options.	<u>Device manufacturer</u> Todd Davis[§]	Thank you for your perspective.
11	The following device manufacturers, associations and societies, or healthcare organizations suggested references as starting points for evidence.	<u>Device manufacturers</u> Todd Davis[§] Charles Schneider[††] <u>Associations and societies</u> Farshad Ahadian[†] (Sharon Kneebone) Keri Kramer[‡] <u>Healthcare organization</u> Lauren Platt McDonald[**] (Teddi McGuire)	The scope of the citations suggested was discussed with the HTAP during topic refinement, prior to publishing the final KQ and PICOTS, all public comments. The program's preference was to keep the scope of the update consistent with that of the prior report. Comparison of different SCS modes of operation, waveforms or frequencies was not part

			of the final review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS. All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS. Reasons for study exclusion at full text are in the appendix.
12	The following associations or healthcare organizations expressed concern that the AAI team lacks clinical experience, that clinicians were not involved in the report, or other concerns related to clinical experience.	Associations and societies Farshad Ahadian[†] (Sharon Kneebone) Healthcare organization Lauren Platt McDonald[**] (Teddi McGuire)	Clinicians with expertise in pain management and in systematic review methodology were involved in topic refinement and provided input on clinical questions posed by the SR team throughout report development. Clinical expert peer review and internal review were obtained on the DRAFT report and incorporated into the final report.
13	Concerns over the 2018 review. Particularly that it did not lead to coverage of SCS.	Associations and societies Farshad Ahadian[†] (Sharon Kneebone) Healthcare organization Lauren Platt McDonald[**] (Teddi McGuire)	Thank you for sharing your perspective. Comments pertaining to formulation of policy do not require a response by the evidence vendor.
14.	Suggestion to include real world studies.	Associations and societies Keri Kramer[‡] Device manufacturer Charles Schneider[††]	Prospective comparative nonrandomized studies of intervention (NRSI) that control for confounding that meet other inclusion criteria were considered and included. NRSIs designed to evaluate safety or harms were included.
15	Specifically included attachments of economic studies.	Associations and societies Keri Kramer[‡]	All citations suggested by commenters (at all stages) were reviewed against the final KQ and PICOTS.

			Reasons for study exclusion at full text are in the appendix in the report
16	Question 1: We would like to request the following be added: What is the evidence of short and long term effectiveness safety of low frequency spinal cord stimulation compared with high frequency spinal cord stimulation? We would like to see this included and considered as there are peer reviewed publications and Level I long term data available. There is data available in peer reviewed publications from an RCT that compared low frequency SCS therapy in one device to other high frequency SCS in a completely different device. Payers often request comparative, head-to-head, studies of devices and including this question will be important to the evaluation.	David Caraway‡‡ (Sandeep Patil)	Comments related to scope comparing different SCS methods or devices were discussed with the HTAP during topic refinement. The program's preference was to keep the scope of the update consistent with that of the prior report. Comparison of different SCS modes of operation, waveforms or frequencies was not part of the final review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS. To the extent that long term comparative data are available comparing SCS with placebo/sham, CMM or other non SCS/non neuromodulation strategies these would be included.
17	Question 2: We would like to request the following be added: What is the evidence of safety of low frequency spinal cord stimulation compared with high frequency spinal cord stimulation?	Device manufacturer David Caraway‡‡ (Sandeep Patil)	Comparison of different SCS modes of operation, waveforms or frequencies was not part of the final review scope based on discussion with the HTAP prior to finalization of KQ and PICOTS.
18	We would like to request that in the new review, WA HTA conduct a sub-analysis by SCS systems and their approved indications. Not all SCS devices have been evaluated for safety and efficacy, or FDA approved in the same patient populations.	Device manufacturer David Caraway‡‡ (Sandeep Patil)	Results are separated by condition and SCS type. Sub-analysis was not possible. A list of FDA devices, characteristics and indications reported in each study are included in the Appendix G (Tables G6-G10). Appendix K lists FDA approved devices and approved indications.

19	Under what conditions would HTA assessments of spinal cord stimulation recommend coverage through programs administered by the Washington State Department of Labor & Industries?	Device manufacturer David Caraway‡‡ (Sandeep Patil)	This was brought to the attention of the HTAP during topic refinement, prior to finalization of KQ and scope. As this is a policy question/issue, it requires no response from the vendor.

AAI = Aggregate Analytics Inc.; AHRQ = Agency for Healthcare Research and Quality; CMM = Conventional medical management; HCA = Health Care Authority; HTA = Health Technology Assessment; HTAP = Health Technology Assessment Program; KQ = Key question; RCT = Randomized control trial; SCS = Spinal cord stimulator.

* Associated with and/or on behalf of Medtronic.

† Associated with and/or on behalf of American Academy of Pain Medicine.

‡ Associated with and/or on behalf of North American Neuromodulation Society.

§ Associated with and/or on behalf of Saluda Medical.

** Associated with and/or on behalf of Providence Health.

†† Associated with and/or on behalf of Boston Scientific.

‡‡ Associated with and/or on behalf of Nevro Corp.

Hamann, Valerie (HCA)

From: David Pitkethly [redacted]
Sent: Thursday, April 27, 2023 10:02 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation (SCS) for HCA Patients

External Email

Dear HCA providers,

I write to you in support of authorizing SCS for patients with chronic, intractable low back pain for which spine surgery is no longer an option. I write to you as an 87 year old retired neurosurgeon with a history of low back pain since the age of 20. At age 40 I was found by X-ray to have spondylolisthesis and spondylolysis at my lowest spinal disc (L5-S1). A fusion was performed at L5-S1 and I had no pain for 20 more years. Since about age 60 I have had 5 more lumbar spine operations secondary to disc herniations and osteoporosis. I am left with a fusion from my third lumbar vertebrae to sacrum and severe low back pain for which there is no further indication for invasive surgery. I have used opioid medications when the pain was severe.

On February 9, 2023 I had placement of a Spinal Cord Stimulator. It is still in adjustment phase but my low back pain is improving and my need for pain medications has reduced significantly.

I am fortunate in that I have medical insurance that paid for most of my treatment and for the spinal cord stimulator. There are many citizens of this great state of Washington who do not have the financial resources to afford a SCS and must depend on addicting drugs such as opioids to bring pain levels down to livable levels. Spinal cord stimulators offer relief from truly severe unremitting pain, no more dependence on pain relieving drugs, and an opportunity to reestablish a productive life.

I strongly recommend that the Washington State HCA authorize spinal cord stimulation for patients that qualify for this important and life changing treatment.

David Pitkethly MD

Sent from Mail for Windows

Hamann, Valerie (HCA)

From: John Hatheway [redacted]
Sent: Saturday, April 29, 2023 11:55 AM
To: HCA ST Health Tech Assessment Prog
Subject: Washington HTA Consideration for SCS

External Email

To whom it may concern:

I am an Interventional Pain Medicine physician and own and practice at Northwest Pain Care, PS. I have been practicing in Spokane, WA since 2007. I have taken care of thousands of Washington residents with chronic pain. I have also witnessed first hand the negative effects that opioids have had upon some of these patients.

In the case of Washington State L & I, Medicaid, and Uniform Regence covered patients, treatment has been extremely limited and frustrating. I have seen hundreds, if not thousands of state insured patients with debilitating chronic pain that were candidates for implantable therapies (spinal cord stimulation and Intrathecal drug delivery) that have been denied access to these therapies. Medicare and Medicaid(in other states) as well as the Veterans Hospital and most commercial insurance companies cover these interventions. I have many patients over the years who have had profound improvement in their chronic pain and have substantially improved functional outcomes due to spinal cord stimulation and Intrathecal drug delivery.

There is a wealth of evidence for spinal cord stimulation showing significantly improved pain and function. Some of this literature is very new. Some compares SCS to medical managment and newer literature compares new spinal cord stimulation waveforms to traditional spinal cord stimulation waveforms(conventional or tonic). All studies support the safety of this therapy. It is a minimally invasive option for patients who have chronic pain that are not candidates for more invasive options such as surgery. In fact, some studies have shown SCS to be superior to repeat surgery.

There are also studies that have shown negative outcomes with SCS for chronic pain. However, close examination of these studies show flawed UDT designs and flawed conclusions. It is imperative that the state recognize these issues when reviewing such studies.

In terms of cost effectiveness, the only options these state insured patients have is continued use of opioids and endless injections. What is the cost of opioid addiction? What is the cost of the chronic affect of multiple steroid injections, which can lead to osteoporosis and fractures, leading to even more morbidity and mortality. What is the cost of endless emergency room visits and hospital admissions for chronic pain? Lack of treatment for these patients leads to worsening depression, lack of activity, and complete removal from the workforce, all of which increases the cost of care substantially.

Again, most of these state insured patients end up on systemic opioids. What is the literature to support the use of systemic opioids for chronic pain long term? There are no studies to support their use for chronic pain long term. Yet, opioids are commonly approved for chronic pain. The cost associated with the medications themselves and the costs associated with the side effects and addiction alone warrant the use of other adjuvant therapies to treat chronic pain.

I truly hope the HTA examines the existing literature closely and does what is best fore the care of Washington State chronic pain patients.

Best regards,

John A. Hatheway, MD
Northwest Pain Care, PS
[redacted]

Hamann, Valerie (HCA)

From: Emilie Jones [redacted]
Sent: Friday, April 21, 2023 2:48 PM
To: HCA ST Health Tech Assessment Prog
Subject: SCS coverage

External Email

To whom it may concern,
I have practiced at several different institutions throughout Washington State and participated in hundreds of patient care conferences seeking to provide relief to patients with chronic pain. Many of these patients have tried physical therapy, surgery, injections, and all other treatments available. Spinal Cord Stimulation is often recommended as a last treatment option for patients who are suffering.

There are rigorous criteria to quality for spinal cord stimulation as well as a clinical trial to determine if the patient is likely to benefit. The evidence supports the efficacy of SCS with appropriate selection criteria.
Considering the ongoing opioid epidemic in our state I encourage the HTA to allow patient access to Spinal Cord Stimulation.

Sincerely,
Emilie Jones, PT, DPT, MBA
Writing as an individual

Hamann, Valerie (HCA)

From: Loeser, John [redacted]
Sent: Friday, April 21, 2023 9:08 AM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal cord stimulation

External Email

In properly selected patients, spinal cord stimulation can achieve significant pain relief. However, a skilled implanted and management team are required.

Sent from my iPhone

_____

Hamann, Valerie (HCA)

From: Soto, Patrick [redacted]
Sent: Wednesday, May 3, 2023 8:01 AM
To: HCA ST Health Tech Assessment Prog
Subject: HTA and SCS

External Email

To whom it may concern:

I am an Interventional Pain physician and own and practice at Northwest Orthopaedic Specialists. I have been practicing in Spokane, WA since 2008. I have taken care of thousands of Washington and Idaho residents with chronic pain. I have also witnessed first hand the negative effects that opioids have had upon some of these patients.

In the case of Washington State L & I, Medicaid, and Uniform Regence covered patients, treatment has been extremely limited and frustrating. I have seen hundreds, if not thousands of state insured patients with debilitating chronic pain that were candidates for implantable therapies (spinal cord stimulation and Intrathecal drug delivery) that have been denied access to these therapies. Medicare and Medicaid(in other states) as well as the Veterans Hospital and most commercial insurance companies cover these interventions. I have many patients over the years who have had profound improvement in their chronic pain and have substantially improved functional outcomes due to spinal cord stimulation and Intrathecal drug delivery.

There is a wealth of evidence for spinal cord stimulation showing significantly improved pain and function. Some of this literature is very new. Some compares SCS to medical management and newer literature compares new spinal cord stimulation waveforms to traditional spinal cord stimulation waveforms(conventional or tonic). All studies support the safety of this therapy. It is a minimally invasive option for patients who have chronic pain that are not candidates for more invasive options such as surgery. In fact, some studies have shown SCS to be superior to repeat surgery.

There are also studies that have shown negative outcomes with SCS for chronic pain. However, close examination of these studies show flawed UDT designs and flawed conclusions. It is imperative that the state recognize these issues when reviewing such studies.

In terms of cost effectiveness, the only options these state insured patients have is continued use of opioids and endless injections. What is the cost of opioid addiction? What is the cost of the chronic effect of multiple steroid injections, which can lead to osteoporosis and fractures, leading to even more morbidity and mortality. What is the cost of endless emergency room visits and hospital admissions for chronic pain? Lack of treatment for these patients leads to worsening depression, lack of activity, and complete removal from the workforce, all of which increases the cost of care substantially.

Again, most of these state insured patients end up on systemic opioids. What is the literature to support the use of systemic opioids for chronic pain long term? There are no studies to support their use for chronic pain long term. Yet, opioids are commonly approved for chronic pain. The cost associated with the medications themselves and the costs associated with the side effects and addiction alone warrant the use of other adjuvant therapies to treat chronic pain.

I truly hope the HTA examines the existing literature closely and does what is best for the care of Washington State chronic pain patients.

Best regards,

Patrick Soto, DO
Physiatrist

Hamann, Valerie (HCA)

From: Chan, Wendy [CA999] [redacted]
Sent: Tuesday, April 25, 2023 9:21 AM
To: HCA ST Health Tech Assessment Prog
Cc: Myszka, Nate; Ricker, Christine; Joseph, John
Subject: Medtronic Public Comment- WA HTA on SCS Draft Key Questions
Attachments: UC202305100a EN SCS WA State HTA SCS Comments FY23.pdf

External Email

Dear Director Birch and WA HTA Committee,

Medtronic appreciates the opportunity to provide public comment on the proposed questions for WA HTA's reassessment of spinal cord stimulation. (See attachment.)

We support the reassessment of this technology and are providing our comments to best support this process.

Please let me know or Christine Ricker know if you have questions.

Best, Wendy

Wendy Chan, MHA
Vice President, Health Economics, Policy and Reimbursement

Medtronic
Neuromodulation, Pelvic Health, & Neurovascular

[redacted]

Medtronic
Engineering the extraordinary

Medtronic

April 21, 2023

Via online submission at: shtap@hca.wa.gov

RE: State of WA Health Care Authority- 2023 HTA Topic Assessment: Spinal Cord Stimulation (SCS) – Draft Key Questions

Dear Director Birch,

We are writing to provide support for the re-review of spinal cord stimulation (SCS) based on the latest body of clinical evidence confirming this as an appropriate therapy for patients with chronic intractable pain. Local physicians have supported the need for alternatives to treat chronic intractable pain beyond reliance on opioid-based analgesics. SCS provides that alternative, with the technology rapidly advancing with new waveforms resulting in even greater improvements in pain control,[1] as well as an additional indication for the treatment of painful diabetic peripheral neuropathy since the last Health Technology Clinical Committee's (HTCC) review in 2010.

We appreciate the opportunity to provide comments as part of this process.

It is important to note that spinal cord stimulation is often a last resort for patients living with chronic pain and is not recommended by most coverage bodies until patients have tried and failed multiple other treatment options. SCS has long-standing coverage through the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD 160.7), multiple commercial payers, and other state workers' compensation and Medicaid plans. One of the largest local BCBS plans (Premera) covers SCS for the treatment of chronic neuropathic pain of the trunk or limbs resulting from "actual damage to peripheral nerves (such as failed lumbar back surgery syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pain, peripheral neuropathy, or painful diabetic neuropathy)".[2] Both Premera, CMS, and other large health plans include specific criteria for coverage including a trial/evaluation period prior to qualifying for the permanent implant.

SCS demonstrates an improvement in quality of life and provides a treatment option to address the unprecedented opioid crisis in this country. Approximately 9.5 million Americans are misusing opioids with 65 percent doing so to relieve physical pain.[3] Further, an estimated

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[1] Fishman M, Cordner H, Justiz R, Provenzano D, Merrell C, Shah B, Naranjo J, Kim P, Calodney A, Carlson J, Bundschu R, Sanapati M, Mangal V, Vallejo R. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Pract. 2021 Nov;21(8):912-923.

[2] Premera Blue Cross Medical Policy 7.01.546. Spinal Cord and Dorsal Root Ganglion Stimulation. https://www.premera.com/medicalpolicies-individual/7.01.546.pdf#search=scs . Accessed Apr 21, 2023.

[3] Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf. Accessed April 2022.

25 percent of chronic pain patients are misusing prescription oral opioids.[4] While SCS does not treat opioid addiction, it provides patients a way to manage their chronic pain as an alternative or adjunct to oral opioids when conventional therapies and medications, including oral opioids, provide inadequate pain relief or intolerable side effects.

Recommendations

We support the re-review of SCS and agree with the proposed questions to facilitate review.

Regarding the PICOTS Scope, we would suggest clarifying what trial study designs would meet the "Comparators" definition of "medical and/or surgical treatment (appropriate to condition)". The most common comparator in SCS randomized clinical trials is "conservative medical management" (CMM), which includes a broad array of interventions tried and failed before SCS, including but not limited to: medication management (opioid and non-opioid), epidural steroid injections, radiofrequency ablation, physical therapy, and chiropractic care. We would like to confirm that these forms of CMM as a comparator to SCS would be included in the PICOT inclusion criteria under "medical treatment".

Second, we would respectfully suggest that the committee evaluate, rather than exclude, randomized studies which compare different types/modalities of SCS. We realize that the research objective is to evaluate the efficacy of SCS vs. patients not treated with SCS; however, as the therapy technology has advanced significantly in the last decade much of the contemporary evidence is of this study design (randomized comparison of waveforms). It would also be helpful to evaluate real-world evidence from prospect registries and retrospective analyses of real-world data sources as these provide the only sources of long-term follow-up. Evaluation of totality of the evidence, not limited to randomized studies, would allow for a more complete picture of the technologies as they perform in a real-world setting.

Finally, it is important to note that one randomized clinical trial with a significantly flawed design appears to meet the PICOTs criteria as outlined.[5] So that reviewers have full context on this study we point the agency to a letter to the editor of JAMA, authored by seven pain physicians globally.[6] Similarly, a recent retrospective claims analysis of SCS costs was published that had flaws in its analytic design.[7] A letter to the editor was published by a panel of expert pain physicians serving on multiple pain physician societies.[8]

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To assist in your literature review below we provide in Appendix A Level I randomized studies of SCS, as well as an Appendix B of peer-reviewed Cost-Effectiveness literature.

Thank you for the opportunity to submit comments as part of this process. If you have questions, feel free to reach out to me at [redacted] or Christine Ricker (Director, HEPR) at [redacted]

Sincerely,

Wendy Chan

Wendy Chan
Vice President, Health Economics Policy Reimbursement (HEPR)
Neurosciences

Appendix A. Randomized evidence of SCS therapy

Failed Back Surgery Syndrome (FBSS)

Study Name	Comparisons	Reference
PROCESS	SCS vs CMM	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;132(1-2):179-188.
		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;63(4):762-770; discussion 770.
		Eldabe S, Kumar K, Buchser E, Taylor RS. An analysis of the components of pain, function, and health-related quality of life in patients with failed back surgery syndrome treated with spinal cord stimulation or conventional medical management. Neuromodulation. 2010;13(3):201-209.
		Manca A, Eldabe S, Buchser E, Kumar K, Taylor RS. Relationship between health-related quality of life, pain, and functional disability in neuropathic pain patients with failed back surgery syndrome. Value Health. 2010;13(1):95-102.
ESTIMET	Multicolumn vs monocolumn programming	Rigoard P, Billot M, Ingrand P, et al. How Should we Use Multicolumn Spinal Cord Stimulation to Optimize Back Pain Spatial Neural Targeting? A Prospective, Multicenter, Randomized, Double-Blind, Controlled Trial (ESTIMET Study). Neuromodulation. 2021;24(1):86-101.
PROMISE	LD SCS vs OMM	Rigoard P, Basu S, Desai M, et al. Multicolumn spinal cord stimulation for predominant back pain in failed back surgery syndrome patients: a multicenter randomized controlled trial. Pain. 2019;160(6):1410-1420.
SCS Frequency Study	1200Hz vs 3030Hz vs 5882Hz vs sham	Al-Kaisy A, Palmisani S, Pang D, et al. Prospective, Randomized, Sham-Control, Double Blind, Crossover Trial of Subthreshold Spinal Cord Stimulation at Various Kilohertz Frequencies in Subjects Suffering From Failed Back Surgery Syndrome (SCS Frequency Study). Neuromodulation. 2018;21(5):457-465.
PROCO	1kHz vs 4 kHz vs 7kHz vs 10kHz	Thomson SJ, Tavakkolizadeh M, Love-Jones S, et al. Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial. Neuromodulation. 2018;21(1):67-76.
--	LD SCS vs reoperation	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; discussion 106-107.

CMM = conventional medical management; LD = low density; OMM = optimal medical management

Complex Regional Pain Syndrome (CRPS)

Study Name	Comparisons	Reference
--	SCS + PT vs PT alone	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(9):618-624.
		Kemler MA, De Vet 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(1):13-18.
		Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. 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;108(2):292-298.
		van Eijs F, Smits H, Geurts JW, et al. Brush-evoked allodynia predicts outcome of spinal cord stimulation in complex regional pain syndrome type 1. Eur J Pain. 2010;14(2):164-169.
--	BurstDR™ vs LD vs HD vs sham	Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJ. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. Eur J Pain. 2017;21(3):507-519.

HD = high density; LD = low density; PT = physical therapy

Diabetic peripheral neuropathy of the lower extremities

Study Name	Comparisons	Reference
--	SCS vs BMT	Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. Diabetes Care. 2014 Nov;37(11):3016-24.
		van Beek M, Slangen R, Schaper NC, et al. Sustained Treatment Effect of Spinal Cord Stimulation in Painful Diabetic Peripheral Neuropathy: 24-Month Follow-up of a Prospective Two-Center Randomized Controlled Trial. Diabetes Care. 2015 Sep;38(9):e132-4.
		van Beek M, Geurts JW, Slangen R, et al. Severity of Neuropathy Is Associated With Long-term Spinal Cord Stimulation Outcome in Painful Diabetic Peripheral Neuropathy: Five-Year Follow-up of a Prospective Two-Center Clinical Trial. Diabetes Care. 2018 Jan;41(1):32-38.
--	SCS vs CMP	de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. Pain. 2014 Nov;155(11):2426-31.
		Duarte RV, Andronis L, Lenders MW, de Vos CC. Quality of life increases in patients with painful diabetic

		neuropathy following treatment with spinal cord stimulation. Qual Life Res. 2016 Jul;25(7):1771-7.

BMT = best medical treatment; CMP = conventional medical practice; NA = not applicable

Mixed indications

Study Name	Comparisons	Reference
DTM™ SCS RCT	DTM™ SCS vs LD SCS	Fishman M, Cordner H, Justiz R, et al. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. *Pain Pract.* 2021;21(8):912-923.
--	40-60 Hz vs 1kHz vs clustered tonic vs sham	Sokal P, Malukiewicz A, Kieronska S, et al. Sub-Perception and Supra-Perception Spinal Cord Stimulation in Chronic Pain Syndrome: A Randomized, Semi-Double-Blind, Crossover, Placebo-Controlled Trial. *J Clin Med.* 2020;9(9):1-15.
WHISPER	Subperception SCS (≤ 1.2kHz) vs supraperception SCS	North J, Loudermilk E, Lee A, et al. Outcomes of a Multicenter, Prospective, Crossover, Randomized Controlled Trial Evaluating Subperception Spinal Cord Stimulation at ≤1.2 kHz in Previously Implanted Subjects. *Neuromodulation.* 2020;23(1):102-108.
--	Subperception SCS (1kHz) vs conventional SCS	North JM, Hong KJ, Cho PY. Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation in Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial. Neuromodulation. 2016;19(7):731-737.
RestoreSensor Study	LD with AdaptiveStim™ vs LD without AdaptiveStim™	Schultz DM, Webster L, Kosek P, Dar U, Tan Y, Sun M. Sensor-driven position-adaptive spinal cord stimulation for chronic pain. Pain Physician. 2012;15(1):1-12.

LD = low density; NA = not applicable

Appendix B. Cost-effectiveness studies of SCS therapy

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2. Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology.* 2002;59(8):1203-1209. http://dx.doi.org/10.1212/01.WNL.0000028686.74056.E3
3. Rojo E, Hernandez CP, Martinez NS, et al. Real-world cost-effectiveness analysis of spinal cord stimulation vs conventional therapy in the management of failed back surgery syndrome. *Journal of Pain Research.* 2021;14:3025-3032. http://dx.doi.org/10.2147/jpr.S326092
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11. Manca A, Kumar K, Taylor RS, et al. Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *Eur J Pain.* 2008;12(8):1047-1058. http://dx.doi.org/10.1016/j.ejpain.2008.01.014
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Hamann, Valerie (HCA)

From: Sharon Kneebone [redacted]
Sent: Wednesday, May 3, 2023 1:52 PM
To: HCA ST Health Tech Assessment Prog
Subject: Spinal Cord Stimulation Key Questions Public Comment Letter
Attachments: WA State HTCC_Spinal Cord Stim Comments_05.03.23.pdf

External Email

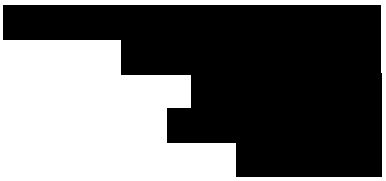
Dear HTCC Committee,

I've attached the American Academy of Pain Medicine's comments addressing the Spinal Cord Stimulation key questions. We thank you for your consideration.

Kind regards,

AAPM
American Academy of Pain Medicine
[redacted]

Sharon H Kneebone, FASAE, CAE
Interim Executive Director
[redacted]



May 3, 2023

Health Technology Clinical Committee
Washington State Health Care Authority
626 8th AVE SE
Olympia, WA 98501

RE: Spinal Cord Stimulation Policy Key Questions

Sent via email to: Shtap@hca.wa.gov

Dear Committee Members,

The American Academy of Pain Medicine (AAPM) has been a preeminent non-profit medical organization for the past 39 years, serving as a champion for pain medicine through education, research, and advocacy. Our volunteer members consist of premier educators, academicians, researchers, and experienced clinicians at top institutions throughout the pain community, including the State of Washington. AAPM is uniquely positioned to evaluate and discuss published evidence in all aspects of the field of pain medicine.

AAPM appreciates the Washington State Health Care Authority (HCA) agreeing to review the updated literature regarding spinal cord stimulation for the treatment of failed back syndrome, post-laminectomy syndrome, complex regional pain syndrome, low back and leg pain, and diabetic peripheral neuropathy. These FDA approved indications of spinal cord stimulation provide a crucial treatment method for carefully selected patients as part of a patient-centered treatment plan. We urge the committee to incorporate both clinical expertise from pain management providers and an updated review of the literature.

The previous 2018 HTCC's *Spinal Cord Stimulation: Assessing Signals for Update*, completed by Aggregate Analytics, Inc. reviewed a broad range of clinical topics, however, the group lacked clinical experience treating patients and concluded spinal cord stimulation could not be approved due to a lack of evidence including small sample sizes, weak and inappropriate comparators, short follow up data, limitations of subjective outcomes, and lack of sham stimulation. The report also concluded that the intervention was less safe than alternative therapies and had high rates of revision surgeries.

We strongly believe that many of these issues have been addressed in the literature published since 2018 and some of the literature prior to that was incorrectly categorized by the paid analyst at Aggregate Analytics. Technological improvements in stimulation patterns (burst, high frequency, and closed loop) have resulted in further improvements in outcomes seen in multiple studies, including a reduction in opioid use and long-term cost effectiveness.

We want to draw particular attention to two recent prospective randomized controlled studies published in high impact journals. In 2021, Peterson et al published in *JAMA Neurology* demonstrates spinal cord stimulation (SCS) can improve pain outcomes, quality of life, and neurological symptoms compared to medical therapy. The second study to note is Mekhail et al. published in 2020 in *Lancet Neurology* demonstrating SCS can improve pain outcomes for patients. Additional randomized controlled studies support SCS for failed back surgical syndrome (Rigoard et al. 2019), post-surgical cervical chronic pain (Amirdelfan et al 2019) nonsurgical back and leg pain (Kapural et al. 2022), as well as neuropathic upper extremity pain (Canos-Verdecho et al 2021) Further studies demonstrate higher odds ratio of returning to work, improved psychological health and opioid reduction.

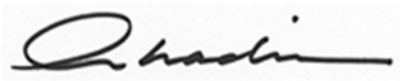
Similarly, the latest studies in larger patient populations demonstrate safety. A study published in *JAMA* for painful diabetic neuropathy, despite a high-risk population, demonstrated a 5% risk of surgical wound related complications (e.g. infection, wound dehiscence). The explant or removal rate was 2% and there were no patients that experienced a neurological deficit related to therapy. In the *Lancet Neurology* study, lead migration was the most common adverse event at 7%. Some data suggests, the rate of adverse events from SCS may be lower than rare, but when compared with the rate of adverse events from opioid therapies they seem trivial.

During the 2018 literature review, the committee agreed the overall value of the spinal cord stimulator implant could not be ascertained. Despite the initial upfront cost of trials and implants, there is a growing body of evidence suggesting a significant improvement in quality-adjusted life years (QALY), willingness-to-pay thresholds for nationalized health care systems, and the EuroQoL-5D (EQ-5D) when compared to conventional medical management. There are at least 10 other high-quality studies that directly measure or model cost effectiveness for this therapy including assessment of different etiologies for painful conditions (see references below).

We believe this treatment is indicated on-label in carefully selected patients as part of a patient centered treatment plan. At present, this treatment is not available for any patients covered under Health Care Authority-sponsored insurance plans but is offered to nearly every other covered group in Washington. This essentially denies pain treatment to a significant proportion of the population in Washington State, a population that includes government employees, state police, firefighters, economically disadvantaged and injured workers. This determination, which is inconsistent with the community standard, represents discrimination against highly vulnerable groups struggling with chronic pain and many times limited access to comprehensive, multidisciplinary pain care.

AAPM strongly urges the committee to re-evaluate the evidence for spinal cord stimulation and carefully incorporate clinical experience into their assessment along with a close examination of updated literature and improvement in spinal cord technology since the previous 2018 decision.

Sincerely,



Farshad Ahadian, MD
President
American Academy of Pain Medicine.

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Hamann, Valerie (HCA)

From: Keri Kramer NEUROMOD [redacted]
Sent: Wednesday, May 3, 2023 12:39 PM
To: HCA ST Health Tech Assessment Prog
Subject: Response to Washington State HCA public comment on Spinal Cord Stimulation
Attachments: NANS Commentary to Washington State SCS May 2023.pdf; Economics of Neuromodulation.pdf

External Email

To whom it may concern:

Please find attached our answers to the four key questions posted regarding spinal cord stimulation. We appreciate the opportunity to provide comment and would be pleased to engage with HCA leadership on any questions you might have about the attached or SCS generally.

I am also attaching a review of existing economic evaluations on neuromodulation to be published in June's *Regional Anesthesia and Pain Medicine* as a resource worth reviewing.

Sincerely,
Keri

Keri Kramer
Chief Executive Officer
North American Neuromodulation Society
[redacted]

[redacted]

NORTH AMERICAN NEUROMODULATION SOCIETY

[redacted]

Submitted May 3, 2023

On behalf of the more than 1,700 members of the North American Neuromodulation Society (NANS), we greatly appreciate the opportunity to submit comments regarding the re-review of Spinal Cord Stimulation (SCS) for the use of chronic pain. NANS is a multi-specialty association dedicated to the development and promotion of the highest standards for the field of neuromodulation. Our membership consists of neurosurgeons, anesthesiologists, neurologists, engineers and other scientists and health care providers, all dedicated to improving the care our patients receive when dealing with chronic neurologic disorders.

We understand that since the last review in 2010, there have been multiple publications regarding spinal cord stimulation and its efficacy and that an appropriate update is necessary at this time.

Chronic pain is, and continues to be, a major problem in our country, affecting an estimated 20.9% of U.S. adults according to the recently released CDC report (1). Health care utilization related to chronic pain continues to grow (2). Treatments for persistent chronic pain are limited and when left untreated can significantly impact quality of life and can worsen depression and anxiety, often times leaving patients hopeless and isolated (3). When conservative non-pharmacological treatment and non-opioid treatments fail, effective treatment options are limited, expensive and/or carry significant risks. For example, for years physicians have used opioids to treat chronic pain, but unfortunately the risk of chronic opioid therapy is high and there is no evidence to support the long-term use of opioids for chronic pain (3). From prior randomized controlled trials (RCT), we have seen that SCS is more effective than reoperation, and certainly carries less risk when compared with surgery (5). SCS, then, when used appropriately and when other treatments fail is an important weapon in the battle against chronic pain.

Given the tremendous number of articles in support of SCS, we are looking forward to the findings of the PICOTS review but would ask this agency to consider the following:

1. With regard to comparators, it is important to include conventional medical management and surgical treatment but we respectfully disagree excluding RCTs that compare SCS waveforms. From prior RCTs with older waveforms, SCS has proven to be an effective treatment (5). It is then reasonable to conclude that with newer waveforms being more effective than traditional tonic waveforms, that newer waveforms would be at least as effective when comparing with conventional medical management and/or surgery.

2. While RCTs are the "gold standard" when assessing treatments, we would like to suggest the inclusion of real world studies as well given their ability to capture patients over a longer period of time than RCTs. Real world studies can help inform clinical practice and have shown that SCS is a valuable modality in chronic pain patients (7).

3. Emphasizing that the quality of recent review articles and RCTs regarding SCS are highly flawed. Specifically, a recent RCT by Hara et al, has been justifiably highly criticized by multiple pain physicians and societies (8).

4. The cost-effectiveness of SCS compared with other medical or surgical options that do not include neuromodulation depends on the specific conditions being treated and the individual patient's circumstances. There is a significant body of research on the cost-effectiveness of SCS compared with other treatments for various chronic pain conditions, including failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), and peripheral arterial disease (PAD).

   Health-economic FBSS studies show that SCS is more cost-effective than conventional medical management or reoperation (9). Moreover, SCS was associated with favorable outcomes. Compared with conventional therapy, SCS resulted in shorter hospital stays and lower complication rates and health care costs at 90 days (10). Additionally, SCS with conventional medical management (CMM) is cost-effective compared with CMM alone in the management of FBSS, CRPS, and PAD (11). Finally, SCS was less expensive and more effective than reoperation in selected failed back-surgery syndrome patients. SCS is most cost-effective when patients forego repeat operation (12).

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Hamann, Valerie (HCA)

From: Schneider, Charles [redacted]
Sent: Tuesday, May 2, 2023 5:30 PM
To: HCA ST Health Tech Assessment Prog
Cc: Patel, Nilesh MD. MBA
Subject: Washington State HCA Reconsideration of SCS: Public Comment
Attachments: Boston Scientific Comment_SCS Reconsideration Draft Questions_02May2023.pdf

External Email

Thank you for your request for public comment relating to questions to be asked when reconsidering the Agency's health technology assessment of spinal cord stimulation. On behalf of Boston Scientific, Inc. please find attached summary comments and references for your consideration. We would welcome the opportunity to provide additional information or schedule time to meet if that would prove valuable to the State of Washington.

With kind regards,

Charles Schneider, Vice President
Healthcare Economics & Market Access

[redacted]

Boston Scientific
Advancing science for life™

May 2, 2023

Via Electronic Submission: shtap@hca.wa.gov

Sue Birch, Director
Washington State Health Care Authority
626 8th Avenue SE, Cherry Street Plaza
Olympia, Washington 98501

RE: WA HCA RECONSIDERATION OF SPINAL CORD STIMULATION TECHNOLOGY ASSESSMENT REQUEST FOR COMMENT ON DRAFT QUESTIONS

Dear Ms. Birch:

Thank you for this opportunity to share comment on questions relating to reconsideration of Washington State Health Care Authority's (HCA) assessment of spinal cord stimulation (SCS)[1]. As the global category leader, Boston Scientific remains committed to serving populations that will meaningfully benefit from our FDA-approved therapies. Our portfolio enables personalized healthcare, providing profound paresthesia-free pain relief in minutes (Metzger 2021[2]). With the ability to provide multiple therapies in one device (Metzger 2020[3], Wallace 2023[4]), patients and their physicians are given options to find the therapy that meets clinical and functional objectives. Examples include opioid reduction or avoidance, positive impact on mental health, functional improvement and quality of life (Adil 2020[5]). Return to work also is an objective discussed in illustrative articles referenced below. (Dauriac-Le Masson, 2023[6]; Moens, 2019[7]; Sundaraj, 2005[8]; Goudman 2020[9] and Ren, 2020[10]).

I. Summary Recommendations

1. Consider the body of peer-reviewed Level I-V published clinical and economic evidence, health system policies and data relevant to heterogeneous populations for whom spinal cord stimulation may be considered by a multi-disciplinary team of clinical experts;

2. Expand questions to include conditions for coverage for which spinal cord stimulation may be covered through Washington State's Department of Labor & Industries; and

3. Clarify PICOTS Scope (Table 1) regarding conservative medical management and comparators viewed acceptable to the HTA.

II. Health Equity Alignment to National Coverage Standards Considering the Body of Published Evidence

Accessibility to spinal cord stimulation aligns with HCA's mission of fair and just opportunity to be as healthy as possible. Injured workers, disabled patients, those insured through Medicaid programs and historically disadvantaged populations are those to be affected by HCA's evidence review and resulting reconsideration of legacy policies.

In its reconsideration of spinal cord stimulation, evidence of equity would not be reviewed under the proposed framework. Nor would consideration of authoritative decisions addressing timely access to indicated treatments for SCS. We applaud HCA for including the comparative clinical effectiveness against conventional medical management, as well as repeat spine surgery (North 2011[11]), but implore consideration of cost effectiveness and opioid reduction which can be achieved through real world data analysis (Fraifeld, 2021[12]), mandating inclusion of broader literature beyond randomized controlled trials (Bates 2019[13]).

- CMS national coverage policy NCD 160.7 enables access to spinal cord stimulation for patients suffering from failed back surgery syndrome, complex regional pain syndrome type I and II. Commercial health plans, managed and integrated care delivery systems, as well as most State Medicaid programs routinely cover trial and permanent implantation of SCS due to the robust body of clinical and economic evidence[14].

- Workers' compensation guidelines including the Official Disability Guidelines (ODG) recommend SCS when conditions have been met[1]. Procedures follow only when the patient has failed at least six months of conservative care but found to be refractory to those treatments. Patients must typically undergo a psychological evaluation, and consultation from a multidisciplinary team of medical experts.

- Published in 2019, the U.S. Department of Health & Human Services Inter-Agency Task Force on Pain Management Best Practices published their comprehensive report detailing recommendations relating to chronic pain[15]. Given the nature and burden associated with refractory neuropathic pain, recommendations including multi-disciplinary, multi-modal, care management relating to injured workers and disabled would be highly relevant to HCA's revised technology assessment of SCS. This includes consideration of clinical options such as SCS aligned to patient-physician objectives. The 2022 CDC opioid guidelines[16] recommendation to include neuromodulation is consistent with the HHS Best Practices report. Importantly, both federal agencies relied upon randomized trials in their conclusions of support. HCA would ideally align its approach to be consistent with these agencies, pain societies and other HTAs.

- Although some progress has been made toward prescribed opioids within the worker's compensation population, the United States Centers for Disease Control and Prevention (CDC) notes opioid use in this population remains problematic. Neumark et al (2018)[17] organized data from 28 states between finding longer-term opioid use associated with disability were three times more likely to continue disability clams compared with non-opioid works compensation cohorts. The Workers Compensation Research Institute also reported opioid prescriptions influences by industry type, company size, age of the injured worker, type of industry and county-level factors (e.g., rural areas had a higher rate of

[1] Work Loss Data Institute ODG recommendations: spinal cord stimulators are recommended on a case-by-case basis for failed back surgery with persistent leg pain that is determined to be related to nerve damage from the initial pathology and/or surgery as confirmed by exam and electrodiagnostic study; and neuropathic pain in post-spinal surgery patients in which there is no evidence of a nociceptive component to symptoms. See also example guidelines published by Magellan (2022) at: https://www1.radmd.com/media/946111/2022-magellan-interventional-pain-management-guidelines.pdf.

opioids dispensed compared with urban areas[18]. Recognition of the heterogeneity of sub-populations covered through workers compensation and disability insurance is encouraged.

- Evidence showing SCS impact on opioid use, morphine milligram equivalents (MME) and SCS as an alternative to addictive drug therapy is available. Questions enabling HCA inclusion of these data is recommended to ensure alternative treatment strategies are equally reviewed in the context of sub-populations affected by assessment outcomes published by HCA.

- Focused research including return-to-work is available and should be captured within assessment of SCS impact within the workers compensation population. For example, Ren et al (2021) evaluated 196 patients from the Ohio Bureau of Workers Compensation receiving SCS between 2007 – 2012. A multivariate logistic regression was run to determine predictors of return-to-work (RTW) status. Regression analyses determined smoking ($p = 0.006$; odds ratio [OR] = 0.260) and body mass index ($p = 0.036$; OR = 0.905) to be negative predictors of RTW status. After implantation, smokers were less likely to RTW after 6-months and had higher pain scores after 6- and 12- months. Both smokers and nonsmokers had significance reductions in opioid use after SCS implantation.

  Moens et al (2018) conducted a systematic literature review through October 2017. Fifteen full-text articles (total articles screened: 2,835) were included. Risk of bias for these articles was scored low. Seven trials provided sufficient data and were judged similar enough to be pooled for meta-analysis on binary outcomes. SCS intervention results in a higher prevalence of patients at work compared with before treatment (odds ratio [OR] 2.15; 95% confidence interval [CI], 1.44-3.21; $I2 = 42\%$; $p < 0.001$). SCS treatment also results in high odds to return to work (OR 29.06; 95% CI, 9.73-86.75; $I2 = 0\%$; $p < 0.001$). Authors therefore concluded SCS had been proven to be an effective approach to stimulate return-to-work in patients with specific chronic pain syndromes.

  Reported from a single center in France, Dauriac-Le Masson et al (2023) evaluated 59 FBSS subjects, reporting a 30.5% RTW rate, improvement in function and reduced unemployment. Authors encourage strict patient selection, multidisciplinary care approach and patient-objectives which included RTW.

As done during HCA's original assessment in 2010[19], we encourage Agency review of information from payers, care providers, technology assessment organizations, federal and state agencies who too have considered spinal cord stimulation within the continuum of care that should be made available to well-selected patients suffering from intractable neuropathic pain.

III. Health Care Authority Technology Assessment: Proposed Question

1. Under what conditions would HTA assessments of spinal cord stimulation recommend coverage through programs administered by the Washington State Department of Labor & Industries?

IV. PICOTS Scope

Table 1 summarizes the scope of review to be undertaken through this contemporary review of spinal cord stimulation. We support evaluation of traditional FDA-approved spinal cord stimulation applications and indication, though would encourage consideration of the full body of published evidence. Peripheral nerve stimulation, dorsal root ganglion, intrathecal pumps, non-approved technologies, and other pain interventions are properly beyond the scope of HTA reconsideration. Similarly, review of waveforms and device-specific claims are not relevant to foundational questions associated with this class of medical technology.

Typically, comparisons to spinal cord stimulation have been conservative medical management (CMM). Notably, patients must typically try and fail CMM prior to SCS consideration. Real world experience and outcomes associated with patient function, mental health, impact on opioid use, cost effectiveness are questions most commonly considered by public and private authorities discussed above.

Thank you again for this opportunity to offer comments. Boston Scientific welcome opportunities to engage further during your review of spinal cord stimulation including discussions around this technology, published clinical and economic evidence as well as use within addressable populations within the State of Washington. Please do not hesitate to contact me directly at [redacted] or by calling [redacted]

Sincerely,

Charles E. Schneider

CHARLES E. SCHNEIDER, Global Vice President
Healthcare Economics & Market Access
Boston Scientific, Inc. Neuromodulation Division

Endnotes

[1] WA State HCA SCS Request for Public Comment: Draft Key Questions at https://www.hca.wa.gov/about-hca/programs-and-initiatives/health-technology-assessment/spinal-cord-stimulation.

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[15] 2019 U.S. Inter-Agency Task Force Report at: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

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APPENDIX: Clinical/peer reviews Received

Peer Reviewer #1: Kim Mauer, MD, Vice Chair for Pain Management & Professor of Anesthesiology and Perioperative Medicine, School of Medicine, Oregon Health and Science University

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Spinal Cord Stimulation** HTA update. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: Spinal cord stimulation rereview: draft evidence report.

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: andrea@aggregate-analytics.com; please cc: erika@aggregate-analytics.com

We will need your review by October 2, 2023, at the latest.

If you have questions or concerns, please contact andrea@aggregate-analytics.com. Thanks!

Reviewer Identification Information

Reviewer Name	**Kim Mauer**
Address	[redacted]
Phone	[redacted]
Fax	[redacted]
E-mail	[redacted]

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

Page ES-1 Line 7

We may not want to say neurostimulation before TENS units. I am not sure if everyone would consider TENS units neurostimulator devices?

Page ES-1 Line 17-18

When we do SCS, the systems work so that the leads go into the epidural space but they don't reach the dorsal columns. The dorsal columns are already there and run the length of the spinal cord. The leads lay in the epidural space on top of the dorsal columns and the stimulation reaches the dorsal columns via epidural space transmission. I am probably not wording that correctly…….

Page Es-1 Line 6

Reoperation reads a little funny to me. Maybe somehow word it that there is a decompression or foraminotomy and then a redo foraminotomy for the nerve root?

Page Es-1 Lines 28-37

Excellent descriptions of high frequency and low frequency SCS systems and technology.

Page Es-2 Line 18

Critically appraise seems a little bit of a weird word but the more I read it, the more it fits in appropriately I think.

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Page 9 Line 3

I really like how you started the section with the updated definition of pain.

Page 9 Line 1

I really like the title "The Condition: Chronic Pain and Neuopathic Pain"

Page 9 Line 33

Neuoropathic pain is underdiagnosed in other conditions than just spinal disease. I am sure we all know that and don't need to know if we need to report that or not?

Page 10 Line 6

I like how we talk about how low back pain contributes to 4.3 million years of disability annually. I also like how we compare it to any other health condition.

Page 11 Line 16

I like the description of CRPS and its demographics.

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page 75 Line 4

I think it was wonderful that you commented on opioid use and that is was not reported in any trial.

Page 2 Line 9

When you start the section 1.4 Key Questions, I really like the chart with the PICOTS/Scope to follow. Makes sense and is easy to follow.ES

Page Es-7 Line 1

I like the way the Key Questions are ordered. For example in Key Question (KQ) 1, I like how you labelled Crossover Trials, Key points…. It makes it easy to follow.

Page Es-12 Line 4

I wonder if we need more explanation of NRSI's. We have in parentheses what it stands for but I wonder if we need more description.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

Page Es-4 Line 2

On the Methods section, one sentence seems a little awkward. Maybe state and to "confirm which outcomes". Add the word "which".

Page Es-5 Line 23

"SOE" starts that sentence but have we defined SOE yet?

Page 69 Line 20

The sentence here that starts "Where" seems a little bit of an odd start to a sentence? Maybe a start that is a little more formal?

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Are the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?

Page ES-6 Line 1

Starting the sentence with “From” seems a little different. Maybe more of a formal sentence to start the section?

Page 69 Line

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Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy)

Page 118 Line All

All of these lines demonstrate the organization which is great.

Page 131 Line 5

I like how we mention that the applicability of the findings to the U.S. healthcare system are unclear. I think it is important that we mention this because it is true in my belief.

Page Line

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

Page 126 Line 33

Under limitations, the sentence starts A long time horizon is employed. I wonder if we can make that sentence a little fuller?

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QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior X ☐

Good ☐

Fair ☐

Poor ☐

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We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

I thought that this form was great. My only thought was if I was supposed to add more columns than provided or if I was just to fill up the amount of spots that were present.

Peer Reviewer #2: Carl Noe, MD, Professor of Department of Pain Management and Anesthesiology & Director of Division of Pain Management, UT Southwestern Medical Center; Medical Director, Eugene McDermott Center for Pain Management.

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Spinal Cord Stimulation** HTA update. Your contribution and time are greatly appreciated.

The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices are available at: Spinal cord stimulation rereview: draft evidence report.

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement. You may also provide a separate document covering the questions posed in this form

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to **focus on the substance/content of the report**.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: andrea@aggregate-analytics.com; please cc: erika@aggregate-analytics.com

We will need your review by October 2, 2023, at the latest.

If you have questions or concerns, please contact andrea@aggregate-analytics.com. Thanks!

Reviewer Identification Information

Reviewer Name	**Carl Noe**
Address	[redacted]
Phone	[redacted]
Fax	
E-mail	[redacted]

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate? Yes, the overview is complete and relevant.
- Topic of assessment is important to address? Yes, the topic is important due to the invasiveness and cost of these therapies.
- Public policy and clinical relevance are well defined? Yes, the patient and societal concerns are covered well.

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BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient? Yes, the literature review is exhaustive and summarized well.

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REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue? Yes, the goals are clear and on target.
- Key questions clearly defined and adequate for achieving aims? Yes, the questions are the right ones and are answered well.
-

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METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate? Yes, the methodology for study selection is sound and thorough.
- Criteria for the inclusion and exclusion of studies is appropriate? Yes, the criteria for inclusion and exclusion are solid.
- Method for risk of bias (ROB) assessment, study quality rating is appropriate and clearly explained? Yes, the risk of bias and study quality rating methods are excellent and clearly explained.
- Data abstraction and analysis/review are adequate? Yes, the data abstraction is extensive and the analysis and review is outstanding.

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RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate? Yes, the amount of detail is sufficient without being overwhelming.
- Key questions are answered? Yes, the key questions are answered with the best available evidence.
- Figures, tables and appendices clear and easy to read? Yes, the tables are excellent.
- Are the major findings clearly stated? Yes, the major findings are clear and substantiated.
- Have gaps in the literature been dealt with adequately? I think so, but gaps in the literature are problematic.

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Summary Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the general conclusions described in the summary points, strength of evidence tables, and Executive Summary valid? (Please note AAI does not suggest implications for policy) Yes, this is a very thorough evaluation.

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well-structured and organized? Yes, it is logically organized.
- Are the main points clearly presented? Yes, it is well written and clear.
- Is it relevant to clinical medicine? Yes, it is very relevant.
- Is it important for public policy or public health? Yes, it provides an excellent summary of a complex topic.

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QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior ☐ **yes**

Good ☐

Fair ☐

Poor ☐

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Comprehensive Evidence-Based Health Technology Assessment Review for the **Spinal Cord Stimulation** HTA update peer review.

This review is a clinically relevant report based on a comprehensive literature review and analysis. It is valuable to policy makers who need to understand a large amount of information about a complex topic.

Specifically, the introduction section provides a complete and relevant overview of the topic. This is important due to the cost and invasiveness of these therapies. The patient and societal concerns are covered well.

The background section includes an exhaustive and comprehensive literature review. This is summarized very well.

The objectives and key questions of the report are clear and on target. The questions are the right ones and are answered well.

The methodology for study selection is sound and thorough. The criteria for inclusion and exclusion are solid. The risk of bias and study quality rating methods are excellent and clearly explained.
The data abstraction is extensive and the analysis and review is outstanding.

The results section is detailed but presented as to not be overwhelming. The key questions are answered with the best available evidence. The tables and figures are excellent.

The major findings are clear and substantiated. Gaps in the literature have been addressed adequately but are always problematic.

The summary provides a very thorough evaluation and conclusions. Overall, the presentation is well organized, well written and clear. It is clinically relevant and provides an excellent summary of a complex subject

We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

The form works well

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