7000 Central Ave NE, RCE385
Minneapolis, MN 55432 USA

Medtronic

July 21, 2017

Medical Advisory Committee
Oregon Workers' Compensation Division
Attention: Juerg Kunz

Subject:
Follow-up on testimony for appropriate use of SCS in Oregon workers' compensation population

Dear Mr. Kunz,

Thank you again for allowing me to testify before the Medical Advisory Committee (Committee) on June 2, 2017. I appreciated the opportunity to be a part of the discussion, and am happy to provide the additional information addressing specific topics from the Committee related to evidence supporting spinal cord stimulation (SCS).

This letter provides information in five general categories following the discussion of the Committee: (1) comments on the SAIF data analysis report; (2) references to guidelines developed by the Neuromodulation Appropriateness Consensus Committee (NACC) ; (3) detail of the UK National Institute for Health and Care Excellence (NICE) technology assessment and guidance for SCS; (4) detail of economic evidence for SCS; and (5) a summary of literature relating to psychological evaluations for SCS therapy. Three of these topics were requested during my testimony, while the topic related to psychological evaluations for SCS therapy is something that I discussed with Dr. Rischitelli following the meeting's adjournment.

Medtronic believes in providing access to SCS for patients for which SCS will provide positive clinical outcomes. The literature below supplements my testimony and our previous literature summary submitted on May 31, 2017.

Neurostimulation for chronic pain is an exciting and evolving field.[1] There are manufacturers with many recent or current clinical studies examining different devices, different ways of applying stimulation to achieve optimal outcomes, and different approaches to best treat chronic pain. This field will continue to change and grow in the future as these studies are published, technologies are introduced, and recommendations are adopted. By taking an approach to balance evidence with technological and clinical innovation, the Committee can ensure appropriate patients in the Oregon workers' compensation program are offered a therapy to improve their pain and quality of life while providing cost-effective therapy.

(1) SAIF Data Analysis Report Comments

We appreciate the SAIF SCS claims analysis, however we have concerns about the coding errors used to identify patients and examine healthcare utilization. This results in non-SCS patients being examined for long-term healthcare use changes.

With SCS therapy, the patient receives a trial or test stimulation, wherein temporary leads are implanted in the epidural space. The patient then goes home and assesses the effectiveness of the therapy for 3 – 10 days. After that time, if a patient had a successful trial as measured by reduced pain, increased function, and improved quality of life, they then may proceed to a permanent implant and are considered SCS patients. This allows the cost for a permanent SCS system to be incurred only in patients for whom the therapy has been demonstrated to be effective.

The SAIF analysis includes both patients who test SCS therapy with a temporary trial stimulation lead, as well as patients receiving long-term SCS therapy via a permanent SCS system. This results in an incorrect attribution of costs and opioid utilization, which are then ascribed to both SCS and non-SCS patients. The modifications to the coding inclusion and exclusion that are found in Appendix A would more accurately identify SCS patients and correctly categorize subsequent healthcare interventions as revision or replacement. There is no evidence that the brief test stimulation period will always result in long-term clinical benefit, as the current analysis assumes.

The analysis also looks at long-term reduction in opioid use, beyond a 12-month period. We believe that reducing opioids in patients is a multi-factorial process that is most successful when addressing topics beyond simply pain relief,[2] and suggest the Committee consider the opioid usage not only at 12-months after implant but also review the 2-year and 3-year data provided by SAIF. The long-term reduction in opioids over this 2- and 3-year period may better reflect the complexity of these patients who have been in pain an average of 12 years prior to implant.[3]

(2) NACC Guidelines

The Neuromodulation Appropriateness Consensus Committee, (NACC) is an independent group of physicians from multiple specialties representing multiple professional societies with the goal of promoting the use of neurostimulation technology in appropriate patients, to increase the overall outcomes of patients receiving this therapy, and to reduce therapy complications in these patients. To that end, NACC has developed (and continues to develop) consensus guidelines on the appropriate use of neurostimulation procedures for chronic pain. A listing of current NACC publications is provided below.[1,4–9]

The first NACC publication included an evidence review of topics such as the effectiveness of SCS for certain indications, implanter training, patient selection, and a check-list of best practices for trialing. [4] More recent topics have focused on ways to reduce complications such as infection and neurological injury, as well as bleeding and coagulation management.[7–9]

We recommend the Committee review the NACC guidelines for insight to the existing body of literature. The Committee may desire to adopt some of the NACC recommendations regarding

implantation requirements, best practices for patient screening, and complication-reduction techniques.

(3) NICE Guidelines

The National Institute for Health and Care Excellence (NICE) produces evidence-based guidelines, technology assessments, and advice for the UK National Health Service. In 2008, NICE performed a technology appraisal to assess the clinical and cost-effectiveness of SCS to identify patient populations in which SCS is clinically-and cost-effective.[10] NICE concluded:

> *Spinal cord stimulation is recommended as a possible treatment for adults with chronic pain of neuropathic origin if they:*
>
> *•continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite standard treatments, and*
>
> *•have had a successful trial of spinal cord stimulation as part of an assessment by a specialist team.*
>
> *Treatment with spinal cord stimulation should only be given after the person has been assessed by a specialist team experienced in assessing and managing people receiving treatment with spinal cord stimulation*[10]*.*

NICE also commissioned a health technology assessment consisting of a systematic evidence review and economic evaluation of SCS therapy.[11] The model found SCS to be cost-effective for both FBSS and CRPS. In addition, the assessment concluded:

> *The evidence suggested that SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. For ischaemic pain, there may need to be selection criteria developed for CLI, and SCS may have clinical benefit for refractory angina short term. Further trials of other types of neuropathic pain or subgroups of ischaemic pain, may be useful.*[11]

In 2013, NICE reviewed this previous decision and recommended the technology appraisal be moved to the "static" list, meaning that the recommendations had a previous full review, and that no additional clinical research would modify the results of the review at that time.[12,13] NICE continues to recommend SCS for individuals with chronic neuropathic pain as a clinically- and cost-effective therapy.

(4) Economic Evidence for SCS

While testifying before the Committee, there was a request to follow-up with the economic evidence of SCS for a variety of indications. Below is a summary of the current health economic evidence for SCS.

A recent publication summarized much of the economic evidence for SCS.[14] We recommend reviewing this, however we recognize that this article includes some key landmark publications that are included in the summary text but missing in the table summary within the article.[15] We encourage the Committee to supplement the recent publication with the summaries below to get a full picture of the current economic evidence of SCS.

Economic Evidence Search Strategy

A literature search was performed via PubMed in June 2017. The search strategy is detailed below, with the specific search wording found in Appendix B.

Economic Evidence Search Results

The PubMed search identified 477 articles that met the search strategy criteria. Abstracts of the articles were reviewed to identify articles of interest to this submission. This resulted in 40 articles that were reviewed for inclusion in this summary

Articles were selected if they were a primary economic evaluation of SCS for chronic pain. Review articles were examined for additional studies that may be missing from the original search.

Articles were further divided into three different categories:

A. Articles that are primary economic analyses, including cost-effectiveness, cost-utility, and cost-benefit for SCS for chronic intractable pain of the trunk and/or limbs, or recent reviews of the primary studies. Indications were selected for on-label use of SCS. (18 articles)
B. Articles that leverage administrative claims data to provide a descriptive analysis of a research question of interest to payers, hospitals, or the healthcare system. (11 articles)
C. Articles that are primary economic analyses such as that in (A) above, but for which the indication under investigation is not on-label for use of SCS in the US. We do not advocate for use of SCS in this population, however the Committee expressly asked about the use of SCS in these populations. These studies are not summarized here, but citations are provided for reference for the Committee's own investigation and review.[a] (11 articles)

These groups are summarized below.

A) Economic analyses, primary research and systematic reviews. Below is a summary of the key cost-effectiveness and health economic studies for SCS for FBSS and for CRPS. Numerous studies and economic models have concluded that SCS to treat FBSS and CRPS is cost-effective, meaning that SCS provides value for money. Some key findings include that SCS for FBSS is cost-effective compared with medical management[16], SCS is less costly and more effective than reoperation[17], SCS for CRPS is cost-effective compared with medical management[18], Failed reoperation followed by SCS was more expensive than starting with SCS and later choosing reoperation[16]. Preventing or reducing complications through advancements in technology and methodology such as that

[a] Medtronic does not market its products for off-label uses, and makes no representations or comment regarding its safety or efficacy.

recommended by the NACC can further reduce the cost of SCS. Also included are recent reviews of primary economic evidence.

Important considerations when reviewing these studies include considering the payment system, the similarity of inclusion or exclusion of patients between studies (i.e. are patients with failed trials included in the intent-to-treat analysis, or is it only patients with successful trials and successful therapy in a study comparator group), and the cost perspective (societal, payer, hospital, etc.).

Economic Analyses of SCS for FBSS

Study	Description	Cost Analyses: Incremental Cost-Effectiveness Ratio (ICER) per Quality-Adjusted Life year (QALY) at Willingness-to-Pay (WTP) Thresholds or Actual/Estimated Costs	Conclusions & Notes
Hoelscher et al, 2017[19]	To review published literature on the cost-effectiveness of SCS therapy	**Review:** The search identified 21 articles examining cost with or without also assessing effectiveness. The majority of articles support that SCS is an effective treatment that represents an efficient use of healthcare resources, and value-for-money.	The majority of studies reviewed conclude that SCS is cost-effective compared with reoperation or conventional medical management (CMM)
Yepes C, et al. 2015[20]	A cost-utility analysis examining the cost-effectiveness of SCS in Colombia. Poster presentation from ISPOR. US Dollars	**SCS vs. Reoperation (FBSS):** • 62% probability that SCS is cost-effective at a WTP of $24,300, as recommended by WHO for developing countries ICER of US $10,293/QALY	SCS has been demonstrated to be cost-effective in many healthcare systems when compared with reoperation.
Zucco F, et al. 2015[21]	To assess the cost-utility of SCS for FBSS in Italy Euros	**SCS vs. CMM (FBSS):** • 80% & 85% probability that SCS is cost-effective at a WTP of €60,000 from payer and society perspective respectively ICER of €38,372 /QALY for societal perspective and €47,000 /QALY for payer perspective	SCS was more cost-effective than CMM in patients with FBSS. The cost-effectiveness of SCS was well below the maximum WTP thresholds.
Annemans et al, 2014[22]	Compares SCS for FBSS using high frequency stimulation parameters (HF-SCS) with CMM and Reoperation, and SCS using high frequency stimulation parameters (HF-SCS) to traditional parameters. British Pounds	**HF-SCS vs. CMM** ICER of £3,153/QALY **HF-SCS vs. Reoperation** ICER of £2,666/QALY **HF-SCS vs. Traditional SCS** HF-SCS for back pain found cost-effective compared with traditional SCS for leg pain in the FBSS patient population • No sensitivity analysis published that estimates probability of cost-effectiveness of SCS at a WTP.	SCS was more cost-effective than both CMM and Reoperation. A comparison of HF-SCS and traditional SCS found HF-SCS to be cost-effective relative to traditional SCS systems. Note: The traditional SCS effectiveness estimation includes patients who were randomized to SCS but failed their initial temporary trial stimulation; they are still analyzed in the traditional SCS group. The HF-SCS effectiveness estimation includes only those who have a successful test stimulation and excludes those who failed the temporary trial stimulation.
Kumar, et al. 2013 [23]	To evaluate the cost-effectiveness of SCS vs. CMM alone in the Canadian healthcare system. 2012 Canadian dollars	**SCS vs. CMM (FBSS):** • 75% probability that SCS is cost-effective at a WTP of CAN $50,000 ICER of CAN $9,293/QALY	SCS was cost-effective compared with CMM in patients with FBSS. The cost-effectiveness of SCS was well below the maximum WTP thresholds.
Hollingworth, et al. 2011 [24]	To estimate cost-effectiveness of SCS among workers' compensation	**Mean medical costs:** SCS: $52,091 Pain clinic: $34,800 Usual care: $23,963 5% of SCS patients, 3% of pain clinic	The reported cost savings of SCS may not be replicated in workers'

Study	Description	Cost Analyses: Incremental Cost-Effectiveness Ratio (ICER) per Quality-Adjusted Life year (QALY) at Willingness-to-Pay (WTP) Thresholds or Actual/Estimated Costs	Conclusions & Notes
	recipients over 24 months. US dollars	patients, and 10% of usual care patients achieved their primary goal at 24 months.	compensation within 2 years after SCS generator implant.
Mekhail N, et al. 2011[25]	To review the clinical and economic evidence of SCS for FBSS.	**Review:** The review summarizes the results from 6 different economic evidence studies on SCS for FBSS. The summarized articles support that SCS is a cost-effective treatment for FBSS that represents an efficient use of healthcare resources, and value-for-money.	SCS for FBSS is cost-effective in carefully-selected patients when compared with CMM or reoperation. This article frames the evidence to support the needs of case managers. This is a good overview of the clinical and economic evidence of SCS through 2010 and is geared towards individual decision-makers at payers.
Taylor, et al. 2010 [16]	To evaluate cost-effectiveness of SCS vs. medical management alone or reoperation in patients with FBSS. Decision analytic cost-utility model developed by the National Institute of Health and Clinical Excellence; 15-year horizon. British pounds	**SCS vs. CMM:** • 89% probability that SCS is cost-effective at a WTP of £20,000 • 98% probability at a WTP of £30,000 ICER of £5,624/QALY **SCS vs. reoperation:** • 82% probability that SCS is cost-effective at a WTP of £20,000 • 93% probability at a WTP of £30,000 ICER of £6,392/QALY	SCS was more cost-effective than CMM or reoperation in patients with FBSS. The cost-effectiveness of SCS was well below the maximum WTP thresholds. A rechargeable battery would be more cost-effective than a non-rechargeable when a patient's stimulation requirements would result in a non-rechargeable battery longevity of <4 years.
Kumar and Bishop. 2009 [26]	To determine costs of 197 patients trialed with SCS; 161 (81.7%) were implanted. Retrospective review. 2007 US dollars	**Average total cost:** Medicare: $32,882 Major insurer (Blue Cross Blue Shield): $57,896 **Failed trial cost:** Medicare: $10,900 Major insurer: $24,686 **Annual average maintenance cost:** Medicare: $5,071 Major insurer: $7,277 **Per-patient complication cost:** Medicare: $1,034 Major insurer: $2,293	SCS costs were less for Medicare patients than for those covered by a major insurance company. Active management of SCS therapy should include allocation for annual maintenance and resolution of complications.
Simpson, et al. 2009 [11]	To explore the cost-effectiveness of SCS in the treatment of chronic pain in the United Kingdom up to 15 years post-implantation. British pounds	**SCS vs. CMM:** • 80% probability that SCS is cost-effective at a WTP of £20,000 • > 95% probability at a WTP of £30,000 ICER of £9155/QALY **SCS vs. reoperation:** • 90% probability that SCS is cost-effective at a WTP of £20,000 • 98% probability at a WTP of £30,000 ICER of £7954/QALY	SCS dominated CMM and reoperation as the most cost-effective option when device longevity was >7 years. SCS achieved "economic dominance" by conferring better treatment success and more QALYs at a lower cost than alternative treatments.
Manca A, et al. 2008[27]	A cost-consequence analysis exploring the cost of SCS for FBSS compared with CMM from the PROCESS RCT. Canadian dollars, Euros	**SCS vs. CMM at 6 months:** **Mean per-patient cost:** SCS: CAN$19,486; 12,653 euros) CMM: (CAN$3994; 2594 euros) **Mean difference in per-patient quality of life (EQ-5D) gain:** SCS group gained a mean EQ-5D score difference of 0.25 [p < 0.001] at 3-months and 0.21 [p < 0.001] at 6-months	SCS + CMM compared with CMM alone has higher costs to the healthcare system, but patients also experience improvements in quality-of-life.
Hornberger J, et al. 2008[28]	A cost-effectiveness analysis of rechargeable vs. non-rechargeable SCS systems	**SCS Rechargeable vs. Non-rechargeable:** The use of a rechargeable SCS system could save up to US $150,000 over a patient's lifetime when compared with non-rechargeable SCS system.	Rechargeable SCS systems are cost-effective in patients who are good candidates for rechargeable systems.

Study	Description	Cost Analyses: Incremental Cost-Effectiveness Ratio (ICER) per Quality-Adjusted Life year (QALY) at Willingness-to-Pay (WTP) Thresholds or Actual/Estimated Costs	Conclusions & Notes
North, et al. 2007[17]	To analyze cost-effectiveness of SCS vs. reoperation. Hospitalization and professional charges tracked over 4 years for 40 of 50 patients in a prospective RCT. US dollars	**Mean per-patient cost (intention-to-treat analysis):** SCS: $31,530 Reoperation: $38,160 **Treatment cost:** SCS: $48,357 (7/14 patients) Reoperation: $105,928 (2/8 patients) **Mean per-patient cost for patients who crossed from original treatment:** Reoperation to SCS: $117,901 (5/13 patients) SCS to reoperation: $260,584 **SCS vs. reoperation:** • 72% probability that SCS is cost-effective at a WTP of $40,000	SCS was more effective and less expensive than reoperation. Failed reoperation followed by SCS was more expensive than starting with SCS and later choosing reoperation.
Kumar, et al. 2006[29]	To calculate actual healthcare costs for complications of SCS in 160 consecutive patients over 10-years; 51 complications occurred in 42 patients. 2005 Canadian dollars	**Mean cost for SCS implantation:** $23,205/patient **Mean annual maintenance cost (uncomplicated case):** $3,609, including INS replacement every 4 years **Mean cost to rectify a complication over a 10-year period:** $7,092 (range $130 to $22,406) **Mean cost to explant an SCS system:** $1,739	Preventing or reducing complications through advancements in technology and methodology helps reduce the cost of SCS.
Taylor RJ, et al. 2005[30]	To assess the cost-effectiveness of SCS for FBSS 2003 Euros	**SCS vs. CMM:** SCS was dominant to CMM over the lifetime of a patient (i.e. SCS is more effective and less costly). SCS was more costly than CMM in a short-term horizon, but was also more effective.	SCS is less costly and more effective than CMM when using a long-term horizon (patient lifetime). SCS is more costly and more effective than CMM when using a short-term time horizon. SCS benefits should be considered over the lifetime of a SCS device.
Kumar, et al. 2002[31]	To calculate actual 5-year costs for treating FBSS with SCS (n = 60) or medical management alone (n = 44). Canadian dollars	**Mean total and (annual) costs:** SCS: $29,123 ($5,825/yr) CMM: $38,029 ($7,606/yr)	Higher costs in the CMM group reflect greater use of healthcare resources (medications, rehabilitation, other pain-control therapies). At 2.5 years, the costs of SCS became less than for CMM.

Economic Analyses of SCS for CRPS

Study	Description	Cost Analyses: Incremental Cost-Effectiveness Ratio (ICER) per Quality-Adjusted Life year (QALY) at Willingness-to-Pay (WTP) Thresholds or Actual/Estimated Costs	Conclusions
Kumar, et al. 2013[23]	To evaluate the cost-effectiveness of SCS vs. CMM alone in the Canadian healthcare system. 2012 Canadian dollars	**SCS vs. CMM (CRPS):** • 89% probability that SCS is cost-effective at a WTP of CAN $50,000 ICER of CAN $11,216/QALY	SCS was more cost-effective than CMM in patients with CRPS. The cost-effectiveness of SCS was well below the maximum WTP thresholds.

Study	Description	Cost Analyses: Incremental Cost-Effectiveness Ratio (ICER) per Quality-Adjusted Life year (QALY) at Willingness-to-Pay (WTP) Thresholds or Actual/Estimated Costs	Conclusions
Kemler, et al. 2010[18]	To compare SCS to medical management alone. Decision analytic cost-utility model developed by the National Institute of Health and Clinical Excellence; 15-year time frame. British pounds	**SCS vs. CMM:** • 87% probability that SCS is cost-effective at a WTP of £30,000 ICER of £3,562/QALY	SCS was more cost-effective than CMM in treating CRPS. When the longevity of an INS is ≤4 years, a rechargeable (and initially more expensive) INS lasting more than 9 years is more cost-effective than a nonrechargeable INS.
Simpson, et al. 2009[11]	To explore the cost-effectiveness of SCS in the treatment of chronic pain in the United Kingdom up to 15 years post implantation. British pounds	**SCS vs. CMM:** • > 40% probability that SCS is cost- effective at a WTP of £20,000 • > 60% at a WTP of £30,000 ICER of £18,881/QALY	SCS dominated CMM as the most cost-effective option.
Kumar, et al. 2006[29]	To calculate actual healthcare costs for complications of SCS in 160 consecutive patients over 10-years; 51 complications occurred in 42 patients. 2005 Canadian dollars	**Mean cost for SCS implantation:** $23,205/patient **Mean annual maintenance cost (uncomplicated case):** $3,609, including INS replacement every 4 years **Mean cost to rectify a complication over a 10-year period:** $7,092 (range $130 to $22,406) **Mean cost to explant an SCS system:** $1,739	Preventing or reducing complications through advancements in technology and methodology helps reduce the cost of SCS.
Kemler and Furnee. 2002[32]	To calculate lifetime costs for 54 CRPS patients in the Netherlands. Euros	**SCS plus PT vs. PT:** Lifetime costs for SCS plus PT (€171,153) were lower than for PT alone (€229,624), regardless of the figure selected, discount rate, implantation rate, and complication rate.	Lifetime costs for SCS plus PT were 25% lower than for PT alone.

B) Administrative Claims Analysis. Claims data can be used to examine the real-world use of health interventions and procedures, and to understand the impact of comorbidities, healthcare utilization, cost, and complications as you follow patients throughout the healthcare system.

There is an emerging body of literature utilizing claims data to answer specific questions on SCS and chronic pain. While these are not Level 1 or Level 2 studies on clinical effectiveness, these retrospective studies can answer specific questions of interest to payers and clinicians, and often have much larger sample sizes than other types of prospective clinical trials. Claims analyses can explore the impact of an intervention on healthcare utilization or patient characteristics within the healthcare system, describe patients more likely to receive a complication, and explore the success of a therapy by clinician characteristic. This evidence is useful for clinicians to identify ways to provide care in a cost-efficient way, but also for payers to understand factors that may impact overall cost of care and coverage.

Important considerations when reviewing these studies include considering the year of data relative to the payment system changes and technology availability, and understanding the patient population in the different data sources.

Our search identified 11 administrative claims analyses for SCS. (We excluded studies not exclusive to SCS.) A summary of claims analyses examining SCS therapy are detailed below.

Study	Description	Results	Conclusions
Han JL, et al. 2017[33]	To explore predictors of SCS system explantation Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicaid populations Years: 2007 – 2012	SCS patients with higher baseline costs, higher post-implant pain cost and procedures, increased age, and increased comorbidity profile were more likely to have an SCS system explant. In addition, patients with implants performed by low-volume providers were more likely to receive an explant than those with higher volume implants, suggesting that provider experience may influence the likelihood of explantation.	There are patient and provider characteristics associated with a higher likelihood of explant. Care should be taken to investigate appropriate pain treatment for patients with a higher likelihood of explant.
Murphy KR, et al. 2017[34]	To explore whether implanters with a higher volume of implants have a higher trial-to-implant conversion ratio than lower-volume implanters Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicaid populations Years: 2007 – 2012	Conversion to a permanent implant was more likely for female patients (1.13 [95% CI: 1.05–1.22], p<0.001) and high volume providers (1.12 [95% CI: 1.02–1.22], p=0.014)	High-volume providers had higher trial-to-implant conversion rates than low-volume providers. Provider volume may be a predictor of successful outcomes, and may be considered when referring patients to SCS therapy.
Lad SP, et al. 2016[35]	To explore whether time from pain to SCS impacts post-implant costs and healthcare resource utilization (HCRU) Database: Truven Marketscan, Commercial Claims and Medicare Supplemental populations Years: 2008 – 2013	For each additional year between pain onset to SCS, patients had an increased likelihood of being high utilizers of HCRU after implant including: • 33% more likely to be in High medical expenditures vs. low medical expenditures quartile (OR 1.33 [1.01, 1.77]) • 43% more likely to be in high opioid cost group vs. low opioid cost group • 55% more likely to be in high hospitalization group vs. low hospitalization group	Considering SCS early in the chronic pain care continuum may result in decreased expenditures, lower opioid and healthcare utilization, and increased outcomes.
Petraglia FW, et al. 2016[36]	To quantify the incidence of spinal cord injury (SCI) in SCS, examining both percutaneous and surgical paddle lead types Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicaid populations Years: 2000 – 2009	For SCS, the incidence of SCI was 2.13%, and the incidence of spinal hematoma was 0.71%. There was no statistically significant difference in these complications by lead type.	Overall incidence of SCI is low, and there is no difference in complication rate by lead type.
Desai MJ, et al.2015[37]	To estimate the need for MRI in the SCS implanted population. Database: Truven Marketscan, Commercial	Approximately 82%-84% of SCS-implanted patients are expected to need at least one MR image within 5 years of SCS implant. Further, 59-74% of patients will require a non-spine MR image within 10 years of SCS implant.	There is a need for MR-conditional SCS systems to address future healthcare needs of this patient population.

Study	Description	Results	Conclusions
	Claims and Medicare Supplemental populations Years: 2008 – 2011		
Huang KT, et al. 2015[38]	To examine the temporary trial lead test to permanent generator implant, and to identify factors associated with a successful SCS trial conversion to implant. Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicaid populations Years: 2000 – 2009	41% of patients (8,982/21,672) receiving a trial in the Truven Marketscan database received a permanent generator implant within 3 months. Some factors associated with SCS system conversion to permanent implant include younger age ($p<0.0001$) and never having a previous SCS trial in the past ($p<0.0001$).	Patient-specific factors may impact successful trial-to-implant conversion. SCS therapy is not fully realized unless the patient receives a permanent generator implant. The authors recommend careful patient selection.
Lad SP et al. 2014[39]	To examine the utilization of SCS and lumbar reoperation in the failed back surgery syndrome patient population, exploring whether people are following the Level 1 evidence from North that recommended SCS as more clinically- and cost-effective than reoperation. Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicare populations Years: 2000 – 2009	For FBSS patients with SCS (n = 395) and reoperation (n = 16,060), the SCS group had lower complications at 30, 60, and 90 days (14.42% vs. 6.51%, $p< 0.0001$). In a matched analysis, SCS had lower hospital length of stay ($p < 0.0001$), and hospital charges ($p= 0.0162$) at index compared with reoperation patients. There was no significant difference in charge for outpatient, emergency department, and medication charges or 2-year cost.	SCS appears to be underutilized in the FBSS population, even while demonstrating lower complication rates and shorter hospital length-of-stay than reoperation.
Missios S et al. 2014[40]	To examine the socioeconomic characteristics of patients with access to SCS therapy to those without access to SCS therapy in an outpatient setting. Database: State Ambulatory Surgery Databases and State Inpatient Databases, respectively, for New York, California, Florida, and North Carolina Years: 2005 – 2008	Patients were more likely to have outpatient access to SCS therapy when they were male (OR 1.22), Caucasian (1.25), while patients with a higher comorbidity index (OR 0.36) and public insurance (0.75) were more likely to access SCS in an inpatient setting. Total charge for SCS in the outpatient setting was significantly lower than in the inpatient setting ($60,624 vs $22,288).	Further investigation is needed to understand how to resolve the socioeconomic disparities in access to care.
Babu R et al. 2013[41]	To explore costs, healthcare utilization for SCS patients with percutaneous lead implantation compared with SCS patients with surgical paddle lead implantation. Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicaid populations Years: 2000 – 2009	Patients in both groups had similar healthcare costs. Percutaneous lead implant patients were more likely to undergo reoperation at two year (6.3% vs. 3.5%, $p = 0.0056$) and five year timeframes, while patients with surgical paddle leads were more likely to develop a complication post-implant (3.4% vs. 2.2%, $p = 0.0005$).	In older technology, SCS patients had similar long-term healthcare costs regardless of the type of permanent lead. There were differences in healthcare revision and complication rates, with no one type of lead providing an advantage in healthcare utilization.

Study	Description	Results	Conclusions
Huang KT et al. 2013[42]	To evaluate how insurance type impacts outcomes after SCS surgery. Database: Truven Marketscan, Commercial Claims, Medicare Supplemental, and Medicare populations Years: 2000 – 2009	Both the commercial and Medicaid groups had similar two-year reoperation rates and 30- and 90-day complication rates. Medicaid patients had higher medication prescriptions, emergency visits, and length of stay. Commercial patients had higher overall costs.	Insurance status seems to have more of an impact on cost and other healthcare utilization than it does on SCS therapy-related healthcare follow-up. Socioeconomic status appears to influence outcomes and utilization after SCS surgery.
Lad SP et al. 2010[43]	To characterize trends in inpatient SCS implantation Database: AHRQ Healthcare Cost and Utilization Project (HCUP) Years: 1993 – 2006	Length of stay decreased from 1993 (4.0 days) to 2006 (2.1 days) for inpatient SCS placement. The cost of surgery increased from 1993 to 2006. (Note: these were not inflation-adjusted as in many other economic analyses)	Cost and clinical effectiveness are both useful factors to consider when studying SCS.

C) Economic Analyses of other indications. The Committee requested evidence for indications that are not currently on-label for Medtronic. There are many articles available in the literature that examine the cost-effectiveness of SCS in indications such as angina, and diabetic peripheral neuropathy. Citations are listed in the references, and are available to the Committee should there be interest in further examining this literature, however they are not summarized here.[44–54]

(5) Psychological Evaluations and Patient Selection

Following the June Committee meeting, I spoke with Dr. Rischitelli about patient selection and best practices to screen patients who are good candidates for SCS compared with those who may have confounding factors that could influence their outcomes. This was touched on in Dr. Ani's testimony.

While SCS therapy use does not require a psychological/behavioral evaluation and the Medtronic Information for Prescribers manual does not mention psychological evaluation, many payers require a patient to receive a psychological evaluation to assess fitness for implantable device therapy and to identify contributing factors related to pain symptoms.

Psychological evaluations and any related behavioral health recommendations are an important tool for payers to use if the service is covered and included in a payer benefit package. We recommend if the Committee requires psychological evaluation as a precondition for SCS therapy, that the benefit package is reviewed to ensure coverage for the required psychological evaluation and that they are paid by workers' compensation carriers.

The appropriateness of psychological evaluations is addressed in the NACC recommendations as being important to appropriate patient selection, and to address any preexisting psychological factors that may influence SCS effectiveness:

> *Some have questioned the appropriateness of implanting patients with active litigation, worker's compensation claims, or obvious secondary gain (138,139). The NACC recommends this be addressed during the psychological assessment and, if any contraindications are documented, further discussions should occur (140). ... The NACC recommends a*

psychological evaluation within less than one year before implementing any neuromodulation therapies (84,85).

In general, the literature recommends psychological assessment prior to implanting SCS therapy. The assessment should use standardized measures including mental health, social risk factors, and pain therapy expectations. Most of the published evidence associates preexisting psychosocial pathology with reduced SCS efficacy.[55] However, some reports find no association between SCS efficacy and preexisting psychosocial risks.[56] Others note that patient expectations, which can be explored within the psychological evaluation process, can be important indicators for a successful outcome.[57] In general, studies found presurgical somatization, depression, anxiety, and poor coping were useful in predicting poor response. However, Doleys stated that "the relationship between psychological factors, pain reduction, and improved function and QOL is highly variable and improvement in one area may not be associated with improvement in others."[58] There are additional articles that also mention the presence of psychological evaluations as a component in the success of SCS therapy that can provide further details.[59–76]

Recent evidence also supports the appropriate use of psychological therapy to address pain, opioid use, and depression amongst post-surgical patients, finding acceptance and commitment therapy was associated with reductions in pain, pain interference, pain catastrophizing, anxiety, opioid use, and depressed mood compared with patients in the group receiving no therapy.[2] Availability of behavioral health services after implant may help to achieve better outcomes and a reduction in opioid utilization when compared to patients without access to this treatment.

Thank you again for the opportunity to testify and to provide additional evidence to further refine the Committee's recommendations. We believe that the literature supports providing workers' compensation patients access to SCS based upon appropriate patient selection. This mirrors the coverage by other payers, and best addresses reducing pain, increasing function, and improving quality of life for eligible patients.

Please contact me if you have any questions.

Sincerely,

Alissa Doth
Senior Program Manager, Health Economics & Outcomes Research
Medtronic Restorative Therapies Group
763-526-8217
alissa.doth@medtronic.com

Appendix A: Recommended SAIF Coding Correction

The current SAIF claims analysis incorrectly includes patients who are not receiving long-term SCS therapy. This results in an incorrect assessment of long-term costs, procedural follow-up, and outcome attribution.

To understand the error in patient identification in the study and the related coding corrections, an understanding of the timeframe of a typical SCS patient and the associated procedures and CPT codes will be helpful.

First, an SCS patient typically receives a "trial" or "test stimulation". This allows the patient and clinician to assess that SCS does indeed meet the goal of reducing pain, increasing function, and improving the patient quality-of-life. It also helps to ensure that a patient has appropriate expectations that it will improve one or more of those outcomes by 50%, but will not "cure" the pain. The trial is identified by CPT 63650 or CPT 63655.[b] Trial stimulation allows the patient, payer, and provider to ensure that the expense of an SCS generator system is only incurred for patients who will benefit the most from the therapy.

If the test stimulation is successful, a patient will then receive a permanent system implant, consisting of a generator implant and one or more leads. This is where a patient is typically considered to be receiving SCS therapy, as the clinical studies and benefits have been shown for the permanent implant. The generator is identified by CPT 63685 and the leads are identified by CPT 63650 or CPT 63655. Patients are typically considered to be receiving the full benefits of SCS therapy when they receive a generator implant. Patients who do not receive the generator are generally not considered to be SCS patients after the removal of the temporary trial leads.

When looking at SCS patients in the claims data, it is helpful to separate patients into those with a successful trial (i.e. those that go on to receive a permanent generator implant) and an unsuccessful trial, particularly when looking at long-term impact of the therapy. Examining the cost and outcomes of these patients separately will help to understand the impact of the therapy on those with successful and unsuccessful trials. There are published claims analyses that also use this methodology to identify successful SCS implants that can be used as an example for this type of claims analysis, and are summarized in the section about economic evidence below.

We recommend the following groupings be used by SAIF to accurately assess the SCS patient population.

Group: SCS Trial only; not receiving SCS therapy

Criteria and Notes: Payment Year >= 2010
Surgery Service Codes: 63650, 63655
NO evidence of: 63685
Should not be any evidence of 63660, 63663, 63664, 63688, 63661, or 63662, as those codes are only used for permanent implant revision, removal, or replacement.

[b] Medtronic leads are approved for test stimulation using CPT 63650, though other manufacturers may have labeling allowing for test stimulation with a lead that is implanted using CPT 63655.

Group: SCS Generator; receiving SCS therapy. Recommend use this group to examine long-term impact of SCS therapy

Criteria and Notes: Payment Year >= 2010

Surgery Service Codes: 63685

Note: for initial implants and not replacements, the claims will show presence of (63650, 63655) on or before same date of service for (63685)

Revision Service Codes: 63663, 63664

Removal Service Codes: 63661, 63662, 63688

Note: AMA created four new CPT codes specific to revision, replacement, or removal of both percutaneous and surgical leads. The new 2010 CPT codes (63661-63664) are more specific; replacing CPT 63660. CPT 63660 should not have been billed after 1/1/2010, so has been removed from the recommended codes here.

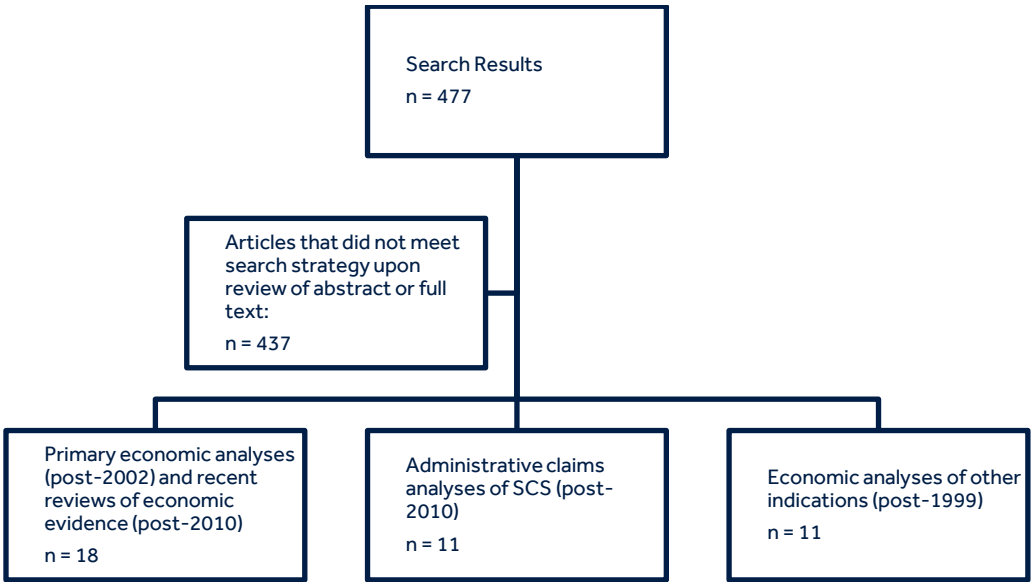
Appendix B: Search Strategy

A search was performed in PubMed on June 10, 2017 using the following search strategy. Articles were selected if they were a primary economic evaluation of SCS for chronic pain. Review articles were examined for additional studies that may be missing from the original search.

Articles were divided into three different categories:

A. Articles that are primary economic analyses and recent reviews of primary economic analyses, including cost-effectiveness, cost-utility, and cost-benefit for SCS for chronic intractable pain of the trunk and/or limbs. Indications were selected for on-label use of SCS.
B. Articles that leverage administrative claims data to provide a descriptive analysis of a research question of interest to payers, hospitals, or the healthcare system.
C. Articles that are primary economic analyses such as that in (A) above, but for which the indication under investigation is not on-label for use of SCS in the US. We do not advocate for use of SCS in this population, however the Committee expressly asked about the use of SCS in these populations. These studies are not summarized here, but citations are provided for reference for the Committee's own investigation and review.[c]

Search strategy:
(((((cost OR costs)) OR (CMS OR HCFA OR Medicare)) OR (cost-effective* OR cost effective* OR cost saving OR cost-saving OR cost-benefit OR cost utility OR cost-utilities)) OR (cost analysis OR cost analyses OR economic OR economics OR cost consequence OR cost-consequence)) AND ((((((((spine OR spinal OR spines)) OR spinal cord) AND electric stimulation therapy) OR spinal cord stimulat*) OR dorsal cord stimulat*) OR neurostimulat*))



[c] Medtronic does not market its products for off-label uses, and makes no representations or comment regarding its safety or efficacy.

Reference List

Reference List

1. Deer TR, Krames E, Mekhail N, et al. The appropriate use of neurostimulation: new and evolving neurostimulation therapies and applicable treatment for chronic pain and selected disease states. Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):599-615; discussion 615.
2. M AA, AZ W, J M. Acceptance and Commitment Therapy to manage pain and opioid use after major surgery: Preliminary outcomes from the Toronto General Hospital .... 2017.
3. SAIF Corporation. Spinal Cord Stimulator Data Analysis and Associated Memorandum. Letter from Brian Null, Sr. Research Analyst, April 28, 2017. Accessed via http://wcd.oregon.gov/medical/mac/Documents/saifmemo.pdf on July 14, 2017.
4. Deer TR, Mekhail N, Provenzano D, et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):515-50; discussion 550.
5. Deer TR, Mekhail N, Provenzano D, et al. The appropriate use of neurostimulation: avoidance and treatment of complications of neurostimulation therapies for the treatment of chronic pain. Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):571-97; discussion 597-8.
6. Deer TR, Mekhail N, Petersen E, et al. The appropriate use of neurostimulation: stimulation of the intracranial and extracranial space and head for chronic pain. Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):551-70; discussion 570.
7. Deer TR, Provenzano DA, Hanes M, et al. The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management. *Neuromodulation*. 2017;20(1):31-50.
8. Deer TR, Lamer TJ, Pope JE, et al. The Neurostimulation Appropriateness Consensus Committee (NACC) Safety Guidelines for the Reduction of Severe Neurological Injury. *Neuromodulation*. 2017;20(1):15-30.
9. Deer TR, Narouze S, Provenzano DA, et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations on Bleeding and Coagulation Management in Neurostimulation Devices. *Neuromodulation*. 2017;20(1):51-62.
10. National Institute for Health and Care Excellence. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE Technology Appraisal

Guidance. October 22, 2008. Accessed via nice.org.uk/guidance/ta159 on June 28, 2017.
11. Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess*. 2009;13(17):iii, ix-x, 1-154.
12. National Institute for Health and Care Excellence (NICE). TA159 Pain (chronic neuropathic or ischaemic) - spinal cord stimulation: Review of NICE Technology Appraisal Guidance No.159; Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. November, 2013. Accessed via https://www.nice.org.uk/guidance/ta159/documents/ta159-pain-chronic-neuropathic-or-ischaemic-spinal-cord-stimulation-review-proposal-november-2013, on June 28, 2017.
13. National Institute for Health and Care Excellence (NICE). NICE Types of Guidelines: Static Guidelines. Accessed via https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/types-of-guideline/static-clinical-guidelines, on June 28 2017.
14. Hoelscher C, Riley J, Wu C, Sharan A. Cost-Effectiveness Data Regarding Spinal Cord Stimulation for Low Back Pain. *Spine (Phila Pa 1976)*. April 2017.
15. Taylor RS, Ryan J, O'Donnell R, Eldabe S, Kumar K, North RB. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain*. 2010;26(6):463-9.
16. Taylor RS, Ryan J, O'Donnell R, Eldabe S, Kumar K, North RB. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain*. 2010;26(6):463-9.
17. North RB, Kidd D, Shipley J, Taylor RS. Spinal cord stimulation versus reoperation for failed back surgery syndrome: a cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery*. 2007;61(2):361-8; discussion 368-9.
18. Kemler MA, Raphael JH, Bentley A, Taylor RS. The cost-effectiveness of spinal cord stimulation for complex regional pain syndrome. *Value Health*. 2010;13(6):735-42.
19. Hoelscher C, Riley J, Wu C, Sharan A. Cost-Effectiveness Data Regarding Spinal Cord Stimulation for Low Back Pain. *Spine (Phila Pa 1976)*. April 2017.
20. Yepes C, Orozco JJ, Valencia J. Cost utility analysis of spinal cord stimulation vs. Reoperation in the treatment of failed back surgery syndrome in colombia. *Value Health*. 2015;18(7):A861.
21. Zucco F, Ciampichini R, Lavano A, et al. Cost-Effectiveness and Cost-Utility Analysis of Spinal Cord Stimulation in Patients With Failed Back Surgery Syndrome: Results From the PRECISE Study. *Neuromodulation*. 2015;18(4):266-76; discussion 276.
22. Annemans L, Van Buyten J-P, Smith T, Al-Kaisy A. Cost effectiveness of a novel 10 kHz high-frequency spinal cord stimulation system in patients with failed back surgery syndrome (FBSS). *J Long Term Eff Med Implants*. 2014;24(2-3):173-83.

23. Kumar K, Rizvi S. Cost-effectiveness of spinal cord stimulation therapy in management of chronic pain. *Pain Med*. 2013;14(11):1631-49.
24. 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;36(24):2076-83.
25. Mekhail N, Wentzel DL, Freeman R, Quadri H. Counting the costs: case management implications of spinal cord stimulation treatment for failed back surgery syndrome. *Prof Case Manag*. 2011;16(1):27-36.
26. Kumar K, Bishop S. Financial impact of spinal cord stimulation on the healthcare budget: a comparative analysis of costs in Canada and the United States. *J Neurosurg Spine*. 2009;10(6):564-73.
27. 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):1047-58.
28. Hornberger J, Kumar K, Verhulst E, Clark MA, Hernandez J. Rechargeable spinal cord stimulation versus non-rechargeable system for patients with failed back surgery syndrome: a cost-consequences analysis. *Clin J Pain*. 2008;24(3):244-52.
29. Kumar K, Wilson JR, Taylor RS, Gupta S. Complications of spinal cord stimulation, suggestions to improve outcome, and financial impact. *J Neurosurg Spine*. 2006;5(3):191-203.
30. Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *Int J Technol Assess Health Care*. 2005;21(3):351-8.
31. Kumar K, Hunter G, Demeria DD. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost-effectiveness analysis. *J Neurosurg*. 2002;97(4):803-10.
32. Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology*. 2002;59(8):1203-9.
33. Han JL, Murphy KR, Hussaini SMQ, et al. Explantation Rates and Healthcare Resource Utilization in Spinal Cord Stimulation. *Neuromodulation*. 2017;20(4):331-339.
34. Murphy KR, Han JL, Hussaini SMQ, et al. The Volume-Outcome Effect: Impact on Trial-to-Permanent Conversion Rates in Spinal Cord Stimulation. *Neuromodulation*. 2017;20(3):256-262.
35. Lad SP, Petraglia FW 3rd, Kent AR, et al. Longer Delay From Chronic Pain to Spinal Cord Stimulation Results in Higher Healthcare Resource Utilization. *Neuromodulation*. 2016;19(5):469-76.
36. Petraglia FW 3rd, Farber SH, Gramer R, et al. The Incidence of Spinal Cord Injury in Implantation of Percutaneous and Paddle Electrodes for Spinal Cord Stimulation. *Neuromodulation*. 2016;19(1):85-90.

37. Desai MJ, Hargens LM, Breitenfeldt MD, et al. The rate of magnetic resonance imaging in patients with spinal cord stimulation. *Spine (Phila Pa 1976)*. 2015;40(9):E531-7.
38. Huang KT, Martin J, Marky A, et al. A national survey of spinal cord stimulation trial-to-permanent conversion rates. *Neuromodulation*. 2015;18(2):133-9; discussion 139-40.
39. Lad SP, Babu R, Bagley JH, et al. Utilization of spinal cord stimulation in patients with failed back surgery syndrome. *Spine (Phila Pa 1976)*. 2014;39(12):E719-27.
40. Missios S, Rahmani R, Bekelis K. Spinal cord stimulators: socioeconomic disparities in four US states. *Neuromodulation*. 2014;17(5):451-5; discussion 455-6.
41. Babu R, Hazzard MA, Huang KT, et al. Outcomes of percutaneous and paddle lead implantation for spinal cord stimulation: a comparative analysis of complications, reoperation rates, and health-care costs. *Neuromodulation*. 2013;16(5):418-26; discussion 426-7.
42. Huang KT, Hazzard MA, Babu R, et al. Insurance disparities in the outcomes of spinal cord stimulation surgery. *Neuromodulation*. 2013;16(5):428-34; discussion 434-5.
43. Lad SP, Kalanithi PS, Arrigo RT, et al. A socioeconomic survey of spinal cord stimulation (SCS) surgery. *Neuromodulation*. 2010;13(4):265-8; discussion 269.
44. Slangen R, Faber CG, Schaper NC, 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):405-414.
45. Eldabe S, Thomson S, Duarte R, et al. The Effectiveness and Cost-Effectiveness of Spinal Cord Stimulation for Refractory Angina (RASCAL Study): A Pilot Randomized Controlled Trial. *Neuromodulation*. 2016;19(1):60-70.
46. Bondesson SM, Jakobsson U, Edvinsson L, Hallberg IR. Hospital utilization and costs for spinal cord stimulation compared with enhanced external counterpulsation for refractory angina pectoris. *J Eval Clin Pract*. 2013;19(1):139-47.
47. Dyer MT, Goldsmith KA, Khan SN, et al. Clinical and cost-effectiveness analysis of an open label, single-centre, randomised trial of spinal cord stimulation (SCS) versus percutaneous myocardial laser revascularisation (PMR) in patients with refractory angina pectoris: The SPiRiT trial. *Trials*. 2008;9:40.
48. Klomp HM, Steyerberg EW, van Urk H, Habbema JDF. Spinal cord stimulation is not cost-effective for non-surgical management of critical limb ischaemia. *Eur J Vasc Endovasc Surg*. 2006;31(5):500-8.
49. Yu W, Maru F, Edner M, Hellstrom K, Kahan T, Persson H. Spinal cord stimulation for refractory angina pectoris: a retrospective analysis of efficacy and cost-benefit. *Coron Artery Dis*. 2004;15(1):31-7.
50. Rasmussen MB, Hole P, Andersen C. Electric Spinal Cord Stimulation (SCS) in the Treatment of Angina Pectoris: A Cost-Utility Analysis. *Neuromodulation*. 2004;7(2):89-96.
51. Andrell P, Ekre O, Eliasson T, et al. Cost-effectiveness of spinal cord stimulation versus coronary artery bypass grafting in patients with severe angina pectoris--long-term results from the ESBY study. *Cardiology*. 2003;99(1):20-4.

52. Merry AF, Smith WM, Anderson DJ, Emmens DJ, Choong CK. Cost-effectiveness of spinal cord stimulation in patients with intractable angina. *N Z Med J*. 2001;114(1130):179-81.
53. Murray S, Carson KG, Ewings PD, Collins PD, James MA. Spinal cord stimulation significantly decreases the need for acute hospital admission for chest pain in patients with refractory angina pectoris. *Heart*. 1999;82(1):89-92.
54. Mekhail NA, Aeschbach A, Stanton-Hicks M. Cost benefit analysis of neurostimulation for chronic pain. *Clin J Pain*. 2004;20(6):462-8.
55. Celestin J, Edwards RR, Jamison RN. Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. *Pain Med*. 2009;10(4):639-53.
56. Wolter T, Fauler I, Kieselbach K. The impact of psychological factors on outcomes for spinal cord stimulation: an analysis with long-term follow-up. *Pain Physician*. 2013;16(3):265-75.
57. Blackburn DR, Romers CC, Copeland LA, et al. Presurgical Psychological Assessments as Correlates of Effectiveness of Spinal Cord Stimulation for Chronic Pain Reduction. *Neuromodulation*. 2016;19(4):422-8.
58. Doleys DM. Psychological factors in spinal cord stimulation therapy: brief review and discussion. *Neurosurg Focus*. 2006;21(6):E1.
59. Campbell CM, Jamison RN, Edwards RR. Psychological screening/phenotyping as predictors for spinal cord stimulation. *Curr Pain Headache Rep*. 2013;17(1):307.
60. Beltrutti D, Lamberto A, Barolat G, et al. The psychological assessment of candidates for spinal cord stimulation for chronic pain management. *Pain Pract*. 2004;4(3):204-21.
61. Stephens KA, Ward A. Patient selection for spinal cord stimulators: mental health perspective. *Curr Pain Headache Rep*. 2014;18(3):398.
62. Sparkes E, Duarte RV, Mann S, Lawrence TR, Raphael JH. Analysis of psychological characteristics impacting spinal cord stimulation treatment outcomes: a prospective assessment. *Pain Physician*. 2015;18(3):E369-77.
63. Fama CA, Chen N, Prusik J, et al. The Use of Preoperative Psychological Evaluations to Predict Spinal Cord Stimulation Success: Our Experience and a Review of the Literature. *Neuromodulation*. 2016;19(4):429-36.
64. Shamji MF, Rodriguez J, Shcharinsky A, Paul D. High Rates of Undiagnosed Psychological Distress Exist in a Referral Population for Spinal Cord Stimulation in the Management of Chronic Pain. *Neuromodulation*. 2016;19(4):414-21.
65. Block AR, Marek RJ, Ben-Porath YS, Kukal D. Associations Between Pre-Implant Psychosocial Factors and Spinal Cord Stimulation Outcome: Evaluation Using the MMPI-2-RF. *Assessment*. 2017;24(1):60-70.
66. De La Cruz P, Fama C, Roth S, et al. Predictors of Spinal Cord Stimulation Success. *Neuromodulation*. 2015;18(7):599-602; discussion 602.
67. Bendinger T, Plunkett N, Poole D, Turnbull D. Psychological Factors as Outcome Predictors for Spinal Cord Stimulation. *Neuromodulation*. 2015;18(6):465-71; discussion 471.

68. Miller RP, Kirkpatrick A. Prognostic value of psychological testing in patients undergoing spinal cord stimulation: a prospective study. *Neurosurgery*. 1997;40(6):1341.
69. Paroli M, Bernini O, De Carolis G, et al. Are Multidimensional Pain Inventory Coping Strategy Profiles Associated with Long-Term Spinal Cord Stimulation Effectiveness? *Pain Med*. May 2017.
70. Block AR, Ben-Porath YS, Marek RJ. Psychological risk factors for poor outcome of spine surgery and spinal cord stimulator implant: a review of the literature and their assessment with the MMPI-2-RF. *Clin Neuropsychol*. 2013;27(1):81-107.
71. North RB, Kidd DH, Wimberly RL, Edwin D. Prognostic value of psychological testing in patients undergoing spinal cord stimulation: a prospective study. *Neurosurgery*. 1996;39(2):301-10; discussion 310-1.
72. Sparkes E, Duarte RV, Raphael JH, Denny E, Ashford RL. Qualitative exploration of psychological factors associated with spinal cord stimulation outcome. *Chronic Illn*. 2012;8(4):239-51.
73. Sparkes E, Raphael JH, Duarte RV, LeMarchand K, Jackson C, Ashford RL. A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. *Pain*. 2010;150(2):284-9.
74. Kumar K, Wilson JR. Factors affecting spinal cord stimulation outcome in chronic benign pain with suggestions to improve success rate. *Acta Neurochir Suppl*. 2007;97(Pt 1):91-9.
75. 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.
76. Olson KA, Bedder MD, Anderson VC, Burchiel KJ, Villanueva MR. Psychological variables associated with outcome of spinal cord stimulation trials. *Neuromodulation*. 1998;1(1):6-13.