

**Washington State Health Care Authority, HTA Program
Key Questions and Background
Spinal Cord Stimulator**

Introduction

HTA has selected Spinal Cord Stimulators for review. An independent vendor will systematically review the available evidence on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. Key questions guide the development of the evidence report. They are posted for public review and comment. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Key Questions

Spinal cord stimulators are surgically implanted devices used to deliver electrical stimulation to the spinal cord to treat pain. When used in adult patients with chronic pain (neuropathic) who have failed alternative therapies:

1. What is the evidence of efficacy and effectiveness of spinal cord stimulation? Including consideration of:
 - a. Short-term and long-term outcomes
 - b. Impact on Function, Pain, quality of life
 - c. Other reported measures including: use of pain medications and opioids, return to work; intensity and duration of use
2. What is the evidence of the safety of spinal cord stimulation? Including consideration of:
 - a. Adverse events type and frequency (mortality, major morbidity, other)
 - b. Revision and removal rates including loss of paresthesia (if not addressed in efficacy)
 - c. Infections
 - d. Lead migration
 - e. Technical malfunctions (e.g., early battery failure, broken leads)
3. What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations? Including consideration of:
 - a. Gender
 - b. Age
 - c. Psychological or psychosocial co-morbidities
 - d. Diagnosis or pain type
 - e. Other patient characteristics or evidence based patient selection criteria
 - f. Provider type, setting or other provider characteristics
 - g. Health care system type, including worker's compensation, Medicaid, state employees
4. What evidence of cost implications and cost-effectiveness of spinal cord stimulators? Including consideration of:
 - a. Costs (direct and indirect) in short term and over expected duration of use
 - b. Replacement

Technology Background

Disease: Chronic pain from conditions such as chronic leg or back pain resulting from failed back surgery syndrome (FBSS), severe nerve related pain or numbness; complex regional pain syndrome (CRPS or reflex sympathetic dystrophy).

Treatments: Chronic pain treatment may include pharmacological treatment, physical therapy, coping skills, antidepressants, cognitive behavioral therapy and supported self-management, to surgical treatment. Treatment strategies generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment often involves a combination of interventions.

Technology: Spinal Cord Stimulation (SCS) involves the administration of electrical impulses in the spinal cord via an implanted pulse generator. Significant questions remain about the safety, efficacy and effectiveness (particularly long term), and the cost effectiveness of SCS.

Public Comment and Response

HTA received five timely public comments, four of which addressed the key questions and their relevance to guide the development of the evidence report; and input from the technology assessment center. HTA reviewed the public comments, consulted technology assessment centers, and gathered follow up information from the nominating agencies. A summary of the input and modification to key questions is below.

Overall topic/other information: The literature base for use of SCS for treatment of ischemic pain was not initially consulted by the evidence vendor, is separate, and represents a substantial increase in the report and would likely result in essentially separate sections or reports on the two pain types. Agencies primarily have experience with, and the concerns raised primarily related to, neuropathic not ischemic pain. The population was modified to remove ischemic. The questions overall were modified to make clearer that the list of subcategories are examples of considerations that effect the key question. An additional note: inclusion of outcomes do not set a threshold for decision, the weight and relevance of outcomes are judged by the clinical committee. Summary of additional comments by question follows.

Question 1: Three commenters felt the subcategories in question 1 should be modified primarily to exclude “return to work” as an outcome on the basis that it was not a relevant outcome; and to expand the pain medications listed.

The pain medication is expanded. Return to work is not excluded as an outcome. This outcome is listed in examples of “other measures”; not within the primary listing of pain, function and quality of life in acknowledgement of some of the limitations mentioned. However, return to work is a patient centered measure reported in clinical trials and addressed as an outcome in several previous HTA reports. It is especially relevant to the effectiveness of the therapy in the context of the purpose of this report which is to inform health purchasing decisions that directly impact public payers whose core missions include returning or enabling their populations to work. The comments related to the limitations of return to work outcomes (e.g. quality, confounding) are acknowledged and are pertinent to the discussion in the evidence report, whereas the overall weight and relevance will be a judgment of the clinical committee, which can be informed by public comment.

Question 2: One commenter requested a comparative analysis with other conventional treatments’ safety. A comprehensive comparative analysis (effectiveness or safety) is beyond the scope of a health technology assessment and outside the scope of the health policy decision that the evidence review is

intended to inform (a decision on SCS, not on comparative coverage for all chronic pain therapies). Relevant context and trial information about safety and adverse events of the technology and utilized comparators, where appropriate, are included in reports.

Question 3: Four commenters had interrelated requests that the question on evidence of differential effect in subpopulations be reformulated to address patient selection and the subcategory of “worker’s compensation” be eliminated. Consideration of evidence based patient selection criteria is added as a subcategory and payer based categories, including worker’s compensation are reworked but not excluded.

Patient selection criteria alone are not an appropriate replacement for the current question which asks broadly about evidence of differential effect or harm. Patient selection criteria presumes efficacy and effectiveness and a net benefit for at least a specified group and is a targeted question most relevant to clinical guideline development. While the current question should already encompass evidence which would also form the basis for patient selection criteria, the subcategory is added.

The current inclusion of worker’s compensation as a consideration under subpopulation generated the most comments based on an assertion that payer source is either not appropriate, confounds effectiveness or blends with patient characteristics. For patient selection criteria alone, these comments may have more relevance, but as explained above, this key question is based on a broader legislative requirement and policy issue about evidence of differential effect. The inclusion of payer based categories is common in research as well assessments (e.g. Medicare or Medicaid beneficiaries). This is especially relevant in evidence reviews designed to assist in health purchasing decisions and for issues of generalizability or effectiveness where impact of variables in the “real world” are studied. To the issue of “blending”, patient categorization for research purposes does not have to be mutually exclusive, and categorization based on exogenous factors may actually reduce confounding. Further, the subcategories are examples; if evidence is found related to any of the subcategories, the evidence report can distinguish as appropriate. Evidence of differential effects, whether based on demographics, clinical measures, employer or payer categories, or other subpopulation descriptors are valued information, from which the committee can determine relevance or weight of the evidence to its decision.

Question 4: One commenter requested that the direct costs subcategory include indirect costs. Subcategory updated to include both.

Curriculum Vitae
Hugh Willison Allen, M.D.

BIOGRAPHICAL

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UNDERGRADUATE TRAINING

1981	Stanford University Stanford, California	B.A.	Human Biology
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GRADUATE TRAINING

1988	University of Southern California Los Angeles, California	M.D.	Alpha Omega Alpha Honor Society
1985	Children's Hospital of Los Angeles Los Angeles, California	Research Fellow	Department of Hematology/Oncology
1987	University of Southern California Medical Center, Los Angeles, California	Research Assistant	Department of Endocrinology

POST GRADUATE TRAINING

1988-89	Brigham and Women's Hospital Harvard Medical School Boston, Massachusetts	House Officer	Internal Medicine
1989-91	Brigham and Women's Hospital Harvard Medical School	Resident	Anesthesiology
1991-92	Brigham and Women's Hospital Harvard Medical School	Chief Resident	Anesthesiology
1991-92	Brigham and Women's Hospital Harvard Medical School	Subspecialty Training	Cardiac Anesthesia: 6 mo Obstetrical Anesthesia: 6 mo

APPOINTMENTS AND POSITIONS

Non-academic:

1981-84	PharmChem Laboratories Palo Alto, California	Director of Research	Toxicology
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Academic:

1992-present	Virginia Mason Medical Center Seattle, Washington	Staff Anesthesiologist Clinical Assistant Professor, U of Washington
1994-present	Virginia Mason Medical Center Seattle, Washington	Section Head, Pain Management
1997-2008	Virginia Mason Medical Center Seattle, Washington	Director, Pain Management Fellowship Program
2000-present	Virginia Mason Medical Center Seattle, Washington	Vice Chief, Department of Anesthesiology

Certification

1996, 2005	Subspecialty Certification in Pain Management American Board of Anesthesiology
1993	Diplomate, American Board of Anesthesiology

Licensure

1992-present	Washington State Medical License
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Scientific and Professional Societies

Alpha Omega Alpha
Washington State Society of Anesthesiology
American Society of Regional Anesthesiology
American Society of Anesthesiology
American Pain Society
International Association for the Study of Pain
International Anesthesia Research Society
American Medical Association
Washington State Medical Association
King County Medical Society

Special Responsibilities

National and State:

Washington-Alaska Cancer Pain Initiative	-Board member, Treasurer, 1996-2002 -President 2002-2003
Cancer Lifeline Medical Advisory Board	-Board Member 1998- present
Washington State Society of Anesthesiology	- Chair Pain Management Committee, 2003-present - President, 2004 to 2006 -Treasurer 2006-2007 -Vice-President, 2003

	-Committee on Office Based Anesthesiology -Educational Chair, 1997-1999
International Anesthesia Research Society	-Reviewer, <i>Anesthesia and Analgesia</i>
Washington State Medical Association	-Industrial Insurance Committee 1998-99
American Society of Anesthesiologists	-Delegate 2004-present -Electronic Media and Information Technology Committee, 2004-2008

Virginia Mason Medical Center:

Cancer Institute Committee	-Member, Pain Management Representative
Virginia Mason Medical Center Personnel Committee	-2000 to 2003
Department of Anesthesiology Committees:	-Education Committee
	-Financial Council Lead Member

Funded Research Projects:

1995	IV Ondansetron in Narcotic Induced PONV	Principle Investigator
1995	Compassionate use of Epidural Clonidine in Severe Cancer Pain	Principle Investigator
1995	Acadesine in Coronary Artery Bypass Grafting	Co-Investigator
1996	Kadian vs. MS Contin for Cancer Pain	Principle Investigator
1996	Granisetron for PONV	Principle Investigator
1997	Use of a Novel Stimulating device on Peripheral Nerves	Co-Investigator
1997	Levobupivacaine in Orthopedic Postoperative Pain Management	Co-Investigator
1998	Levobupivacaine in Total Hip Replacement	Co-Investigator
1998	Encapsulated Bupivacaine in ankle block model	Co-Investigator
1998	Ropivacaine for postoperative analgesia after colectomy	Co-Investigator
1998	Liposomal Epidural Morphine for postoperative pain management	Co-Investigator
1999	Encapsulated bupivacaine in an intercostals block model	Co-Investigator
2000	IDDS vs. MS Contin in Cancer Pain	Primary Investigator
2000-2003	Co-investigator on several small projects related to encapsulated local anesthetics	Co-investigator
2008-2010	Study of Bioness battery-powered microstimulator to treat chronic shoulder pain in post-stroke subjects	Co-investigator

Invited Lectures:

Postoperative Pain Management" Olympic Memorial Hospital, Port Angeles, WA, 11/16/94
"Cancer Pain Management" 28th Annual Cancer Care for the Primary Care Provider, VMMC, 2/24/95
"Anesthetic Blocks for Herpes Zoster" Topics in Primary Care- Dermatology, VMMC 3/8/96
"Pain Management in the ICU Patient" at 3rd Annual Dr. Arthur Wendel Conference, Port Angeles, WA 9/30/96
"Cancer Pain Management" Cancer Center Forum, Virginia Mason Medical Center, Seattle, 1/23/97
"Issues in Acute Pain Management" American Society of Regional Anesthesia Workshops, 2/1/97 San Francisco, 2/8/97 Los Angeles
"Thoracic Epidural Analgesia" American Society of Regional Anesthesia Workshops, 2/1/97 San

Francisco, 2/8/97 Los Angeles
"Things we have learned about reflex sympathetic dystrophy" at American Academy of Pain Management Nurses, Seattle, WA 3/12/97
"Acute Perioperative Pain Management" at 4 th Annual Anesthesia Symposium, Colorado Springs, 4/26/97
"Permanent Epidural Placement and Management" Sleepless in Seattle, Regional Anesthesia. presented 8/2/97 and 8/3/97
"Pain Management" Virginia Mason-Forks, Washington Teleconference 3/18/98
"Cancer Pain Management" ASTRA Preceptorship, 4/14/99, Seattle
"Palm Computers in Medicine" Washington State Soc Anesthesia Fall Meeting. "Computers in Medicine" 9/12/98
"Geriatric Pain Management" VM Regional CME lecture to Sequim Washington, 5/21/98
"Cancer Pain Management" Three Lectures in Odessa, Chernegy, and Kiev, Ukraine as consultant for U.S. Agency for International Development through "Program for Appropriate Technology in Health". 7/21-23/98
"Lower Extremity Blocks for Outpatients" Society for Ambulatory Anesthesia, Annual Meeting, 5/1/99
"Panel on Outpatient Regional Anesthesia" Society for Ambulatory Anesthesia, Annual Meeting, 5/1/99
"Acute Pain Management" ASRA Regional Workshop, Denver, CO 6/5/99
"Truncal Anatomy and Nerve Blocks" ASRA Regional Workshop, Denver, CO 6/5/99
"Pain Management for the Next Millennium Lecture for VMMC Circle benefactors, 6/8/99
"How to Organize a Pain Service" Sleepless in Seattle, Regional Anesthesia 1999 (VMMC organized CME) 7/31/99
"Fluoroscopy for Pain Management" Sleepless in Seattle, Regional Anesthesia 1999 (VMMC organized CME) 7/31/99
"Permanent Epidural Placement and Management" Sleepless in Seattle, Regional Anesthesia 1999 (VMMC organized CME) 7/31/99
"Palmtop Computing in Anesthesiology" American Society of Anesthesiologists, Annual Meeting. 10/12/99
"Pain Management Update" Med-Surg Update: Orthopaedic/Musculoskeletal Focus, VMMC CME 10/25/99
"Anesthesia for the Next Millennium" Port Angeles, Olympic Memorial Hosp. CME. 11/6/99
"Acute Pain Management "ASRA Regional Workshop, Los Angeles, CA 11/13/99
"Lower Extremity Anatomy and Blocks" ASRA Regional Workshop, Denver, Los Angeles, CA 11/13/99
"Acute Pain Management" ASRA Regional Workshop, Sacramento, CA 1/30/00
"Acute Pain Management" ASRA Regional Workshop, Salt Lake City, UT 2/26/00
"Pain Management" Regional Service Teleconference CME to Port Townsend 2/23/00
"Fluoroscopy for Pain Management" ASRA National Meeting, Lecture given twice on 3/30/00

"Pain Management Training Programs" ASRA National Meeting 3/31/00
"Pain Management, issues for internists" VMMC Medicine Housestaff lecture, 4/7/00
"Patient Controlled Epidural Analgesia" Univ. Washington Pain Fellow's lecture, 4/18/00
"Handheld Medical Databases" Society for Technology in Anesthesia, Monterey, CA 10/20/00
"Cancer Pain Management" Virginia Mason Medical Center Grand Rounds, 11/17/00
" Handheld Computers in Medicine" Virginia Mason Medical Center Grand Rounds, 11/4/02
"Billing in postoperative Pain Management" ASRA Annual Meeting, San Diego, 4/5/03
" Advanced Spinal Pain Management" at Virginia Mason CME, "Low back pain for the primary care provider" 4/4/03
"Acute Postoperative Pain Management" Kaiser Southern California CME 5/03
"Pain Management Data Collection with PDA's" American Society of Anesthesiologists Annual Meeting, San Francisco, 10/03
"Informational Website for Academic Anesthesiology: Development issues" Computers In Anesthesiology, Society for Technology in Anesthesiology, Napa, 10/03
"Locoregional Control of Cancer Pain", National Conference on Cancer, Havana, Cuba 10/03
"Interventional Pain Management" VMMC Pain CME, Seattle, WA 11/04
"Pain Management Data Collection with PDA's" American Society of Anesthesiologists Annual Meeting, Las Vegas 10/04
"Point of Care Database" American Society of Anesthesiologists Annual Meeting, Atlanta, 10/05
"Thoracic Epidural Analgesia" Presentation and workshop. Sleepless in Seattle Meeting, Seattle, WA 7/06
"Interventional Pain Management for Cancer Pain" Great Falls, MT 9/06
"Interventional Pain Management for Cancer Pain" Chelan Cancer Conference, Lake Chelan 10/06
"Handheld computing workshop", American Society of Anesthesiologists Annual Meeting 2006-2009
Grand rounds, interventional pain management. VMMC 2007, 2008
"Departmental Intranet Workshop", American Society of Anesthesiologists Annual Meeting, 2009

Published Papers:

1. Neal JM, Wilcox RT, Allen HW, Low DE., Near-total esophagectomy: the influence of standardized multimodal management and intraoperative fluid restriction. *Reg Anesth Pain Med.* 2003 Jul-Aug;28(4):328-34
2. Kopacz, D.J., Bernards, C.M., Allen, H.W., Landau, C., Nandy, P., Lacouture, P., A model to evaluate the pharmacokinetic and pharmacodynamic variables of extended-release products using in vivo tissue microdialysis in humans: bupivacaine-loaded microcapsules. *Anesth Analg.* 2003 Jul;97(1):124-31
3. Allen, H.W., Using Personal Digital Assistants for Pain Management. *Techniques in Regional Anesthesia & Pain Management* 2002;6(4).

4. Kopacz, D.J., J.D. Helman, C.E. Nussbaum, J.N. Hsiang, P.C. Nora, H.W. Allen, *A comparison of epidural levobupivacaine 0.5% with or without epinephrine for lumbar spine surgery*. *Anesth Analg*, 2001. **93**(3): p. 755-60
5. Kopacz, D.J., H.W. Allen, and G.E. Thompson, *A comparison of epidural levobupivacaine 0.75% with racemic bupivacaine for lower abdominal surgery*. *Anesth Analg*, 2000. **90**(3): p. 642-8.
6. Kopacz, D.J., N.E. Sharrock, and H.W. Allen, *A comparison of levobupivacaine 0.125%, fentanyl 4 microg/mL, or their combination for patient-controlled epidural analgesia after major orthopedic surgery*. *Anesth Analg*, 1999. **89**(6): p. 1497-503.
7. Kopacz, D.J. and H.W. Allen, *Accidental intravenous levobupivacaine*. *Anesth Analg*, 1999. **89**(4): p. 1027-9.
8. Liu, S.S., H.W. Allen, and G.L. Olsson, *Patient-controlled epidural analgesia with bupivacaine and fentanyl on hospital wards: prospective experience with 1,030 surgical patients*. *Anesthesiology*, 1998. **88**(3): p. 688-95.
9. Allen, H.W., et al., *Peripheral nerve blocks improve analgesia after total knee replacement surgery*. *Anesth Analg*, 1998. **87**(1): p. 93-7.
10. Liu, S.S., et al., *Respiratory depression with addition of fentanyl to spinal anesthesia [letter; comment]*. *Anesth Analg*, 1997. **85**(6): p. 1416-7.
11. Liu, S.S., et al., *Dose-response characteristics of spinal bupivacaine in volunteers. Clinical implications for ambulatory anesthesia*. *Anesthesiology*, 1996. **85**(4): p. 729-36.
12. Liu, S., et al., *Intravenous versus epidural administration of hydromorphone. Effects on analgesia and recovery after radical retropubic prostatectomy [see comments]*. *Anesthesiology*, 1995. **82**(3): p. 682-8.
13. Kopacz, D.J. and H.W. Allen, *Comparison of needle deviation during regional anesthetic techniques in a laboratory model*. *Anesth Analg*, 1995. **81**(3): p. 630-3.
14. Liu, S., et al., *Comparison of 5% with dextrose, 1.5% with dextrose, and 1.5% dextrose-free lidocaine solutions for spinal anesthesia in human volunteers*. *Anesth Analg*, 1995. **81**(4): p. 697-702.
15. Liu, S., et al., *Fentanyl prolongs lidocaine spinal anesthesia without prolonging recovery*. *Anesth Analg*, 1995. **80**(4): p. 730-4.
16. Thangathurai, D., et al., *The incidence of pruritus after epidural morphine [letter] [see comments]*. *Anaesthesia*, 1988. **43**(12): p. 1055-6.
17. Thangathurai, D., et al., *Epidural morphine and headache secondary to dural puncture [letter]*. *Anaesthesia*, 1988. **43**(6): p. 519.
18. Allen, H.W. and B. Sedgwick, *Detection of ritalinic acid in urine by thin-layer chromatography and gas chromatography*. *J Anal Toxicol*, 1984. **8**(2): p. 61-2.

Books and Chapters:

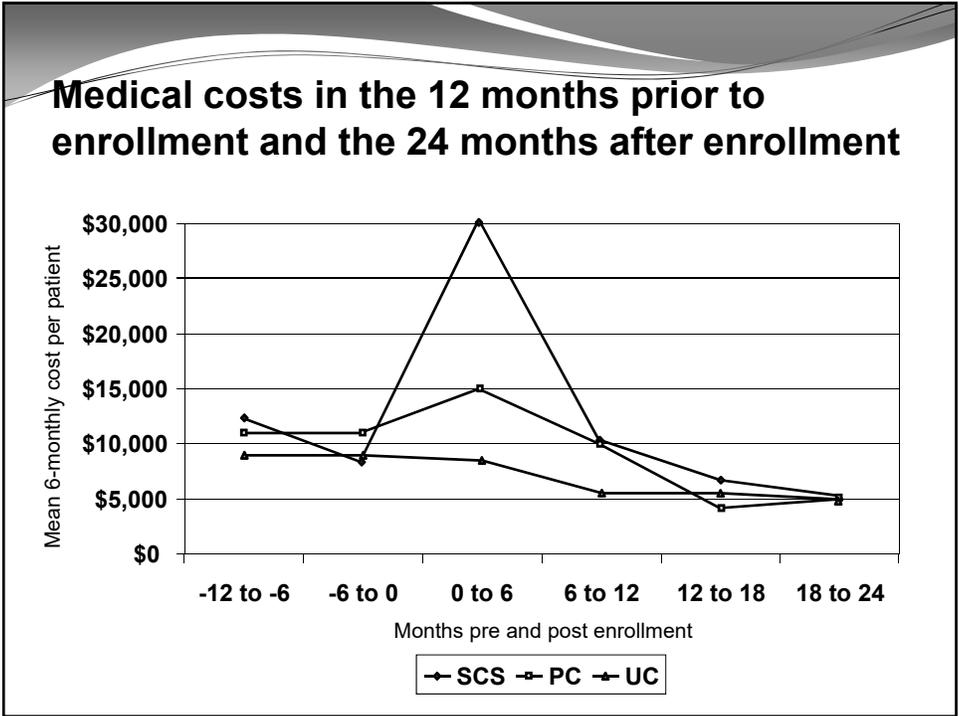
1. Allen, H.W. *Difficult cases in postoperative pain management*. *Seminars in Anesthesia* 16(4): 271-279, 1997

Washington State Study of Spinal Cord Stimulation for Injured Workers with Failed Back Surgery Syndrome: Costs

Judith A. Turner, Ph.D.
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Costs over 24 months after study enrollment

- Medical costs to payer (payments made), including medications, hospitalizations, outpatient visits
- Productivity loss costs (time loss compensation and other payments to workers for inability to work due to their injury)



Costs over 24 months

	SCS trial Mean	PC eval Mean	UC Mean	SCS vs PC	SCS vs UC
Medical	\$52,091	\$34,800	\$23,964	\$17,291	\$28,128
Productivity loss	\$46,546	\$49,540	\$43,328	-\$2,994 (ns)	\$3,218 (ns)
Total	\$98,637	\$84,340	\$67,292	\$14,297 (ns)	\$31,350
Adjusted Total Costs*	\$99,230	\$78,930	\$69,260	\$20,300	\$29,970

*Adjusted for baseline factors associated with costs or the primary outcome at 24 mo.

Summary

- Medical care and productivity loss costs over 24 mo for a patient who received trial SCS were on average \$20,300 higher than for a patient who received a pain clinic evaluation and \$29,970 higher than for a patient who received usual care.
- Additional costs of SCS trials/permanent implants were not counterbalanced by lower medical or productivity loss costs during the 24-mo follow-up.
- The SCS group did not have significantly better pain, function, or opioid use outcomes at 24 mo.
- No evidence SCS was cost-effective for workers' compensation recipients with FBSS in this study.



Agency Medical Director Comments

Spinal Cord Stimulation for Neuropathic
Pain

August 20, 2010



SCS Treatment: Background

- Involves insertion of electrodes into the epidural space
- Electrodes are connected to a surgically implanted pulse generator
- Electrical impulses generated are thought to inhibit the conduction of pain signals to the brain
- Intended to treat pain for many years; not a short-term treatment



Agency Concerns

Safety Concerns (Medium)

Implanted device with risk of infection, morbidity, and death. High risk for further interventions (revision, removal, re-implantation)

Efficacy Concerns (High)

Short term, modest pain relief, no clear improvement in function; no evidence of longer term improvement in pain or function; real world-outcomes worse than RCTs

Cost Concerns (Medium)

Usage and costs escalating rapidly; very high per patient cost



Coverage Overview

- Currently covered by DSHS, PEBB, DOC
- Labor and Industries (L&I)
 - Long-standing non-coverage policy based on no evidence of substantially improved pain AND function (required under WAC); non-coverage decision upheld after cohort study completed Sept, 2008
 - Continuing non-coverage policy based on formal review and advice of statutory Industrial Insurance Medical Advisory Committee (IIMAC)

L&I Evidence Development for Spinal Stimulation

- 1995: commissioned systematic review of SCS literature addressing long-term risks and benefits.
Turner et al, Neurosurgery 1995; Dec 37(6): 1088-95
- 2003: commissioned systematic review of SCS literature addressing effectiveness and complications
Turner et al, Pain 2004; 108: 137-47
- 2004: contracted cohort study of Failed Back Surgery Syndrome(FBSS).
 - 2004-2008: injured workers with FBSS were eligible for treatment with SCS
 - Effectiveness data published, included in report:
Turner et al, Pain 2010; 148: 14-25
- Complete cost study submitted:
Hollingworth et al

L&I Number of Requests for SCS

Requests for SCS during the study period (2004-2008)

- Injured workers meeting study inclusion criteria were enrolled in the study beginning in 2005.
- Continued access to the treatment for workers meeting study criteria until results of study were available.
- Total study and non-study requests shown.

Year	Study	Non-study	Total
2005	84	-	84
2006	69	-	69
2007	35	57	92
2008	0	114	114
Total	188	171	359



Short-Term SCS Implantation Costs

Costs per patient receiving trial + implant +/- revision and removal

- UMP: N=118; \$54,353 (22 mos)
- L&I: N=27; \$38,373 (24 mos)
- DSHS: N=30; \$9706 (2.6 mos)

(Duration observed in administrative data)

Agency SCS costs-total reimbursed*, 2006-2009

- UMP-\$4,686,442
- L&I-\$3,553,608** +
\$575,861 (study administration)
- DSHS-\$254,000

*Costs include only SCS related charges.

**Total n=161 injured workers with at least trial stimulation



Agency Data: Adverse events

2005-2009

- UMP- 23% revision/removal; 28% other adverse events; adverse events account for 17.4% of all costs, and averaged \$24,646/patient (\$13-\$248,000)
- L&I (Turner cohort study)
 - 1 trial patient with severe, life-threatening event
 - Permanent implant-3 superficial, 1 deep infection (14%); 19% revision; 19% removal



Mortality: Coffey et al, Anesthesiology 2009; 111: 881-91

One year unadjusted mortality rates:

- Intrathecal infusion pump-3.89%
- Spinal cord stimulator-1.36%
- Medicare lumbosacral spine surgery-3.52%



Efficacy vs effectiveness

- Efficacy studies- “Can it work under ideal conditions?”
 - Attempt to tightly control potential confounding factors and bias.
 - May not be applicable to many patients seen in everyday practice.
- Effectiveness studies- “Does it work in real-world setting?”
 - Use less stringent eligibility criteria, more often assess health outcomes, and have longer follow-up periods than most efficacy studies.
 - The results of effectiveness studies are more applicable to the average patient than results from the highly selected populations in efficacy studies.

Scientific Evidence: Efficacy & Effectiveness

Study	Condition Longest F/U	Outcomes		Comparator	Sponsor
		Pain	Function		
Kemler 2000, 2004, 2006	CRPS 5 years	-	-	PT	Dutch Health Insurance Council
Kumar 2007, 2008	FBSS 1 year	+	+	CMM	Medtronic
North 2005	FBSS 2.9 +/- 1.1 years	+	-	Re-operation	Medtronic
Turner 2010	FBSS 2 years	-	-	Pain clinic, usual care	L&I



Scientific Evidence: Considerations

- Current evidence is conflicting and limited to relatively short-term
 - Modest pain relief only in short term
 - 3/4 studies with no improvement in function
- Positive studies of efficacy and cost-effectiveness are industry funded and managed
- Invasive technology with high rates of complications (i.e., revision, removal)

Impact of industry sponsorship on studies

“Industry funded studies demonstrated a statistically greater likelihood to report positive results than studies with other funding sources.” **Shah et al, Spine, 2005**

Results:

- 16% had industry support, 13% foundation support, 10% government support, 3% institution support, 58% “not funded”.
- Odds ratio of industry funded reporting positive results 3.3 times ($P < 0.001$) that of other funding sources.



Cost-effectiveness (C/E) evidence

Concerns:

- No long-term efficacy/effectiveness showing SCS reduces pain and improves function
- All studies asserting C/E assume effectiveness over very long-term
- Assumptions are not adequate/reflective of all available evidence
- Example: Taylor & Taylor 2005
 - Assumes 80% trial success
 - One-way sensitivity analyses- not reflective of real-world or RCT experience
 - Multi-way analysis presented only for 'best case'
 - Assumptions based on efficacy data from 1 Level II RCT (North et al.) with 2.5 yrs follow-up.



AMDG Recommendations

Non-coverage due to:

- Safety concerns:
 - Repeat interventions for clinical/technical failure, common
 - Severe infections, death potential
- Very limited efficacy:
 - Only for modest pain relief only in short term
 - 2/3 RCTs with no effect on function
 - No evidence that patient selection (trial results, psychological screening) improves outcomes
- No clear effectiveness in workers comp:
 - Limited benefit with increased opioid use at 6 months, no effect beyond that
- Huge cost per implanted patient
- SCS currently lacks compelling evidence of appropriate benefit (length/type); and has high device complication and removals, and very high cost - not ready yet

Impact of industry sponsorship on studies

Shah et al., Spine 2005:

Objective: to evaluate potential correlations between sponsorship and study outcome.

- Retrospective review of articles published in Spine, January 2002 thru July 2003
- Of 1143, 527 articles included based on area of study (e.g., Anatomy, randomized controlled trial, surgery, etc.) and presence of abstract, materials/methods and conclusion sections
- Results categorized as positive, negative, neutral
- Categorized based on funding type as found in acknowledgement section of each study: Government, Foundation, Institution, Industry, or No Funding

Results:

- 16% had industry support, 13% foundation support, 10% government support, 3% institution support, 58% "not funded"
- Odds ratio of industry funded reporting positive results 3.3 times ($P < 0.001$) that of other funding sources

Conclusion: Industry funded studies demonstrated a statistically greater likelihood to report positive results than studies with other funding sources. Potential explanations for this are biased study design, biased experimental technique, biased result interpretation, or publication bias.

[Industry support and correlation to study outcome for papers published in Spine.](#) Shah RV, Albert TJ, Bruegel-Sanchez V, Vaccaro AR, Hilibrand AS, Grauer JN. Spine 2005 May 1;30(9):1099-104.

Scientific evidence: impact on pain in SCS “responders”

- Marchand et al, Pain 1991; 45: 249-257
 - N=8 “responders” to spinal stimulation
 - Real stimulation vs sham stimulation
 - Mean pain relief from SCS prior to study reported as 63%
 - Mean reduction in pain intensity in study only 23%
 - “The relatively small reduction in clinical pain (less than 30%) must be weighed against the invasive nature of electrode implantation”

Scientific Evidence: Efficacy

3 RCT's, 2 funded by manufacturer

[Kemler et al](#), CRPS; NEJM, 2000; SCS+PT vs PT
6 months-improved pain, **no improved function**
3 years-pain no longer significant (NEJM 2006)

[North et al](#), FBSS; Neurosurgery, 2005; SCS vs reoperation

3 years-more "success" (>50% pain relief and satisfaction, and more crossover to SCS; **no improved function**)

[Kumar, Taylor, North](#), et al, FBSS; Pain, 2007; SCS vs conventional medical management

6 months-improved pain and function

Kumar, Taylor et, Pain 2007;132: 179-188 (PROCESS)

“All logistical aspects of the study were managed and funded by Medtronic Inc. The trial was designed and supervised by a Trial Steering Committee that consisted of four external advisors and two representatives from Medtronic Inc. Data were collected and analysed by Medtronic Inc. under the direction of the committee. The manuscript was written by the independent members who had full, non-restricted access to the data. E. Buchser, R.S. Taylor and the Johns Hopkins University (R. North’s employer) have received financial reimbursement as consultants for Medtronic”

- **Statistical Analysis** – M. Janssens (Medtronic International Trading Sarl Europe)



Taylor, North, et al, The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. Clin J Pain July/Aug 2010; 26: 463-469

“The development of this model and preparation of this manuscript was funded by Medtronic, Inc, Minneapolis, MN. James Ryan's employer, Abacus International, Bicester, UK; Dr Rod Taylor; and The Neuromodulation Foundation, Inc, Baltimore, MD of which Dr Richard B. North is President, have received reimbursement as consultants for Medtronic.”



Spinal Cord Stimulation Technology Assessment

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**Health Technology Clinical Committee Meeting
Washington State Health Technology Assessment Program
Seattle, Washington
August 20, 2010**



Scope of Report

This report evaluates relevant published research describing the use of spinal cord stimulation (SCS) for chronic neuropathic pain

Background



Indications for SCS (FDA)

Chronic intractable pain in the trunk and/or limbs including unilateral or bilateral pain associated with FBSS and intractable low back and leg pain, and for some devices:

CRPS, radicular pain syndrome or radiculopathies resulting in pain, post-laminectomy pain, unsuccessful disc surgery, degenerative disc disease or herniated disc pain refractory to conservative or surgical interventions, peripheral causalgia, epidural fibrosis, arachnoiditis or lumbar adhesive arachnoiditis, and multiple back surgeries.

Potential patients should undergo a period of trial stimulation prior to permanent SCS implantation.

Background



Contraindications for SCS (FDA)

- Failed trial stimulation due to ineffective pain relief
- Poor surgical risks
- Pregnancy
- Active general infections or multiple illnesses
- Inability to operate the SCS system
- Cardiac pacemakers (with specific exceptions and precautions) or cardioverter defibrillators

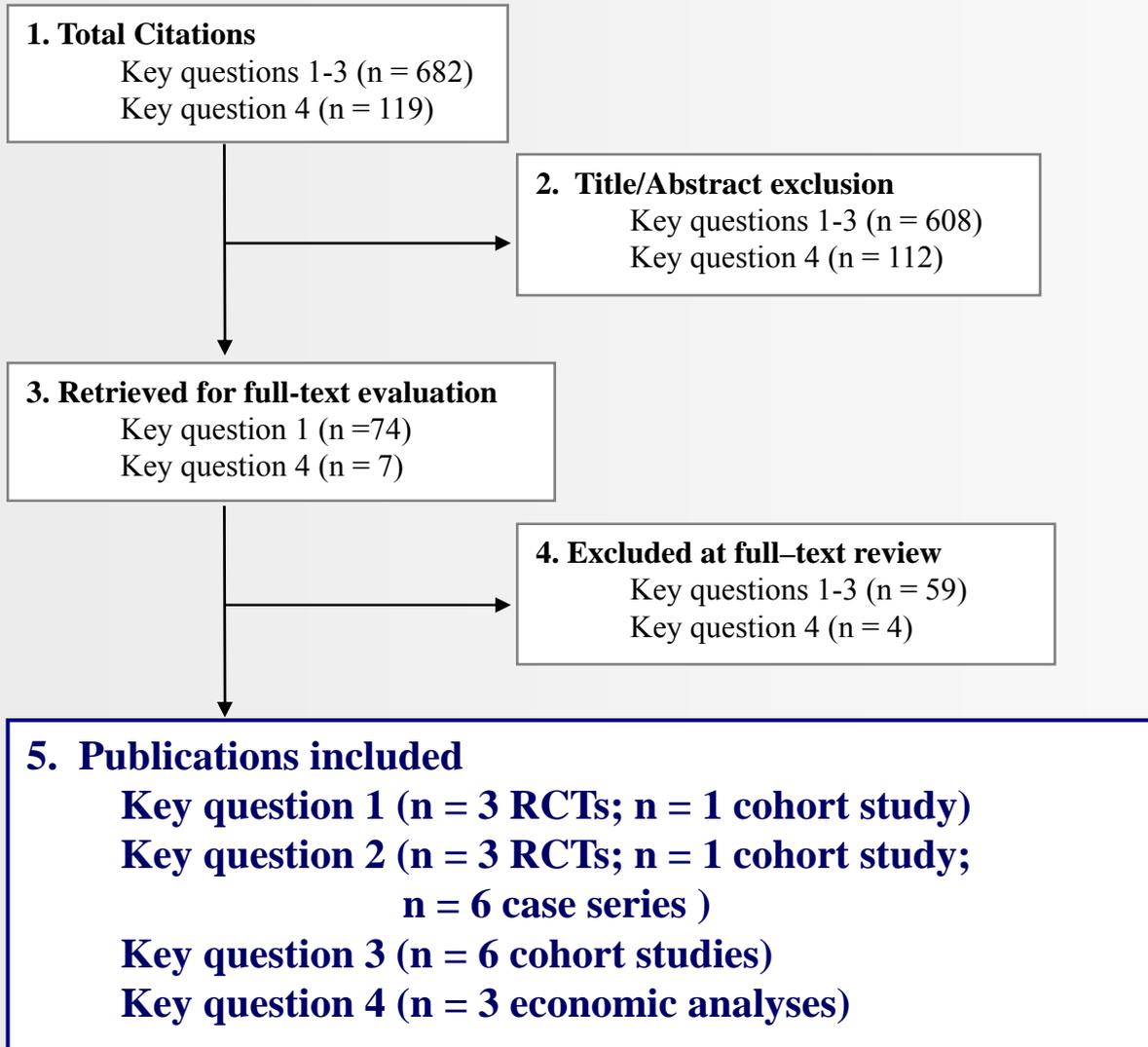
Key Questions



When used in adult patients with chronic neuropathic pain who have failed alternative therapies:

1. What is the evidence of efficacy and effectiveness of SCS?
2. What is the evidence of safety of SCS?
3. What is the evidence that SCS has differential efficacy or safety issues in subpopulations?
4. What is the evidence of cost implications and cost effectiveness of SCS?

Literature Search



Comparative clinical studies



Study	Study Type	Preop diagnosis	Follow-up	Treatment	Patient characteristics	Permanent implant	Study Sponsor
Kemler (2000, 2004, 2008) The Netherlands	RCT	Chronic CRPS I	6 months (100%) 24 months (94%) 60 months (81%)	<ul style="list-style-type: none"> • SCS + PT (n = 36) • PT alone (n = 18) 	N = 56 Mean age: 38 years Sex: 31% male	24/36 (67%)	Dutch Health Insurance Council
Kumar (2007, 2008) Europe, Canada, Australia, Israel	RCT	FBSS with leg pain > back pain	6 months (94%) 12 months (88%)	<ul style="list-style-type: none"> • SCS + CMM (n = 52) • CMM alone (n = 48) 	N = 100 Mean age: 50 years Sex: 51% male	43/52 (83%)	Managed, analyzed (with external direction), & funded by Medtronic
North (2005) Johns Hopkins University	RCT	FBSS with leg pain ≥ back pain	2.9 ± 1.1 years (range: 1.8–5.7) (75%)	<ul style="list-style-type: none"> • SCS (n = 30) • Reoperation (n = 30) 	N = 60 Mean age: 50 years Sex: 50% male	17/24 (71%)	Funded by Medtronic; Johns Hopkins received profit from related sale
Turner (2010) University of Washington	Prospective cohort study	FBSS with leg pain > back pain	6 months (97%) 12 months (93%) 24 months (87%)	<ul style="list-style-type: none"> • SCS (n = 51) • Pain Clinic (n = 39) • Usual Care (n = 68) 	N = 159 Mean age: 44 years Sex: 77% male Open workers' comp claims	27/51 (52%)	Funded by WA State Department of Labor & Industries

Internal Validity



Methodological principle	Kemler 2000, 2004, 2008	Kumar 2007, 2008	North 2005	Turner 2010
Study design				
Randomized controlled trial	✓	✓	✓	
Cohort study				✓
Statement of concealed allocation*	✓	✓	✓	
Intention to treat*	✓	✓	✓	
Independent or blind assessment	✓	✓	✓	✓
Co-interventions applied equally	✓	✓	✓	✓
Complete follow-up of $\geq 80\%$	✓	✓		✓
Adequate sample size	✓	✓	✓	✓
Controlling for possible confounding	✓	✓		✓
Evidence class	I	I	II	II

* Applies to RCTs only

Key Question 1



What is the evidence of efficacy and effectiveness of SCS for the treatment of chronic neuropathic pain compared with other treatments?

Outcomes efficacy/effectiveness

1. "Success" from a composite score
2. Pain relief
3. Function
4. Health-related quality of life
5. Patient satisfaction
6. Global perceived effect (GPE)
7. Medication usage

Key Question 1



Efficacy

Studies that met our inclusion criteria:

3 RCTs:

- CRPS: 1 RCT (Kemler)
- FBSS: 2 RCTs (Kumar, North)

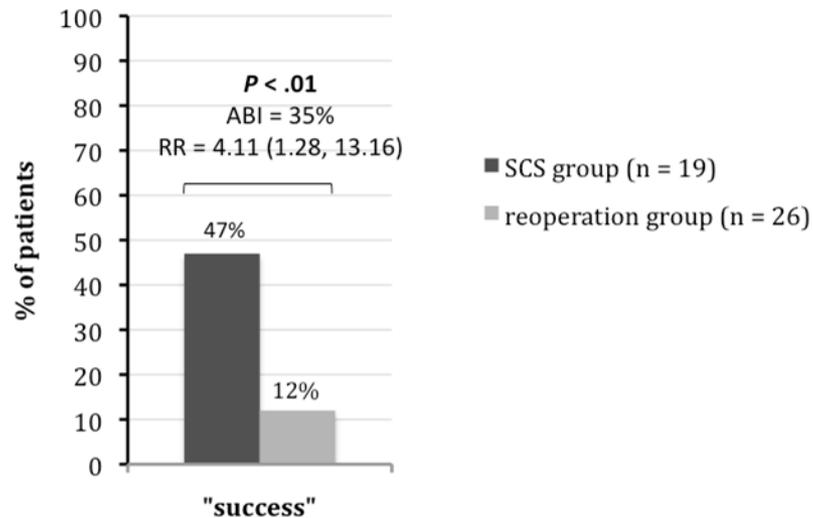
Efficacy– “Success”

1 RCT (FBSS)



“Success” = composite of pain relief $\geq 50\%$ and patient satisfaction

Percent of patients achieving “success”



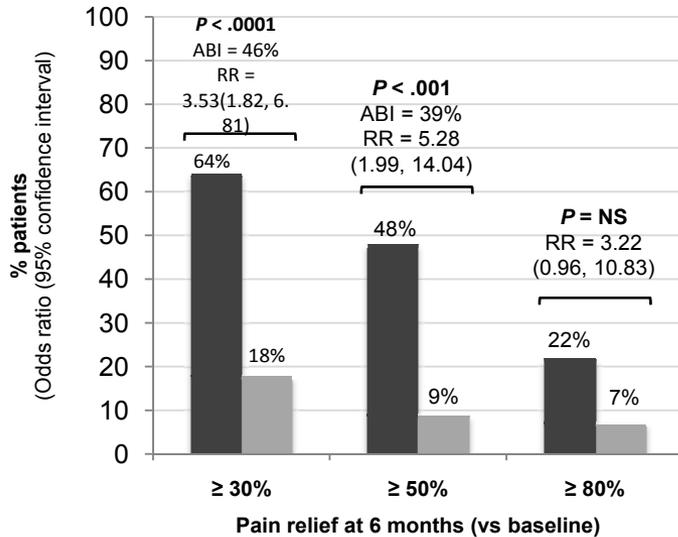


Efficacy– Pain relief (1 of 2)

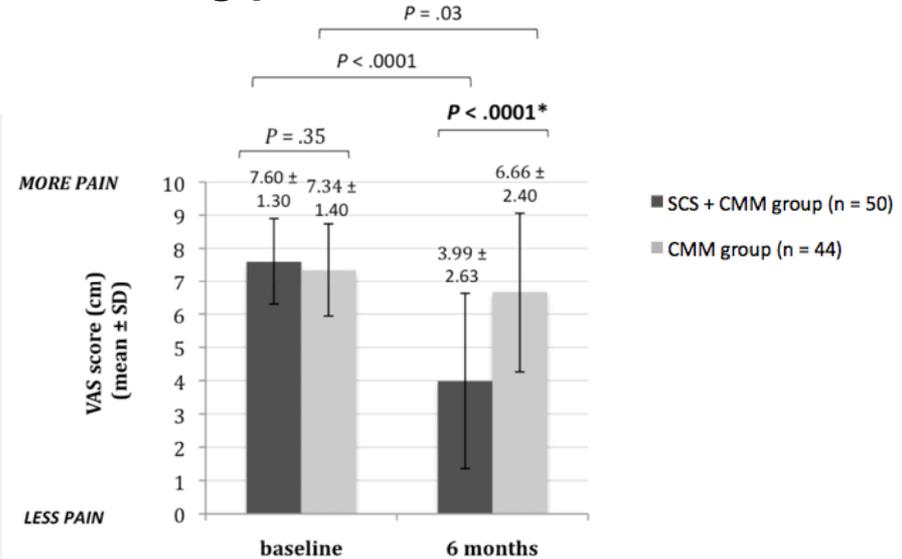
2 RCTs (FBSS, CRPS)

Kumar: FBSS (6 months): leg pain

% of patients achieving pain relief



Mean leg pain VAS



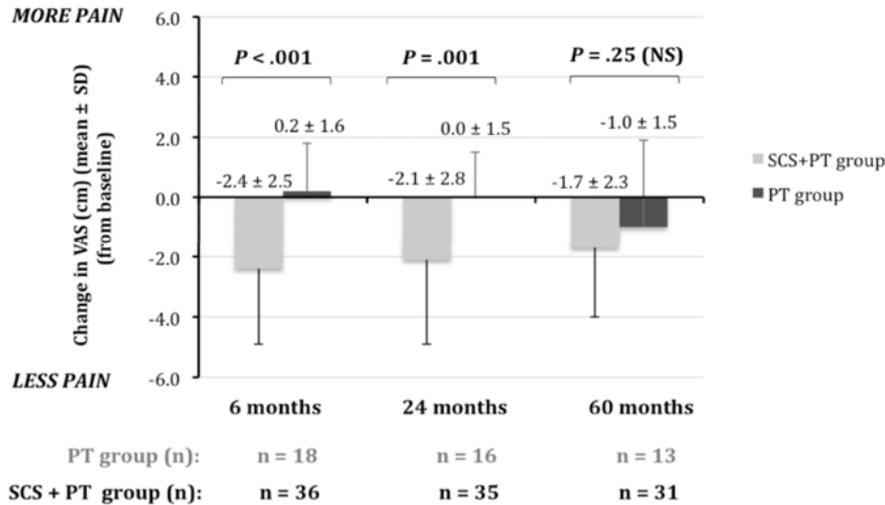
Kumar reported similar improvements in mean back pain VAS scores for SCS patients.



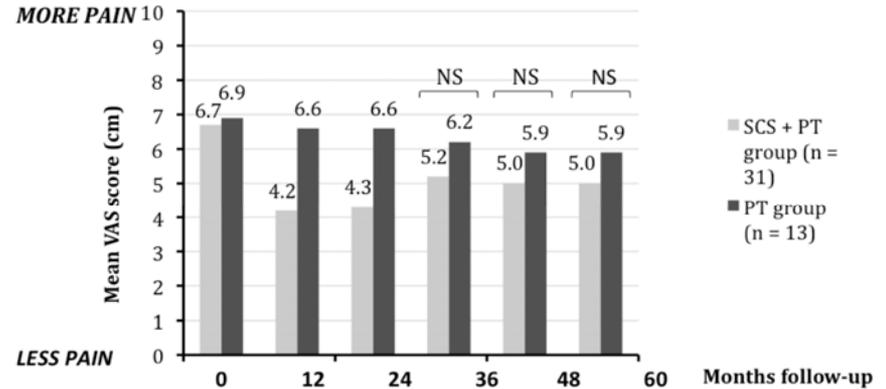
Efficacy– Pain relief (2 of 2)

Kemler: CRPS I (6, 24, & 60 months)

Change in VAS (from baseline)



Mean VAS



Efficacy– Function



Author	Diagnosis	Treatments	Outcome measure	F/U period	Results
Kumar (2007)	FBSS	SCS + CMM vs. CMM	ODI	6 months	SCS: better scores
Kemler (2000, 2004)	CRPS	SCS +PT vs. PT alone	Jebsen hand scores; Kemler foot scores	6 & 24 months	No statistical differences
North (2005)	FBSS	SCS vs. reoperation	Neurological status; Daily activities	2.9 years (mean)	No statistical differences

Efficacy– Quality of Life



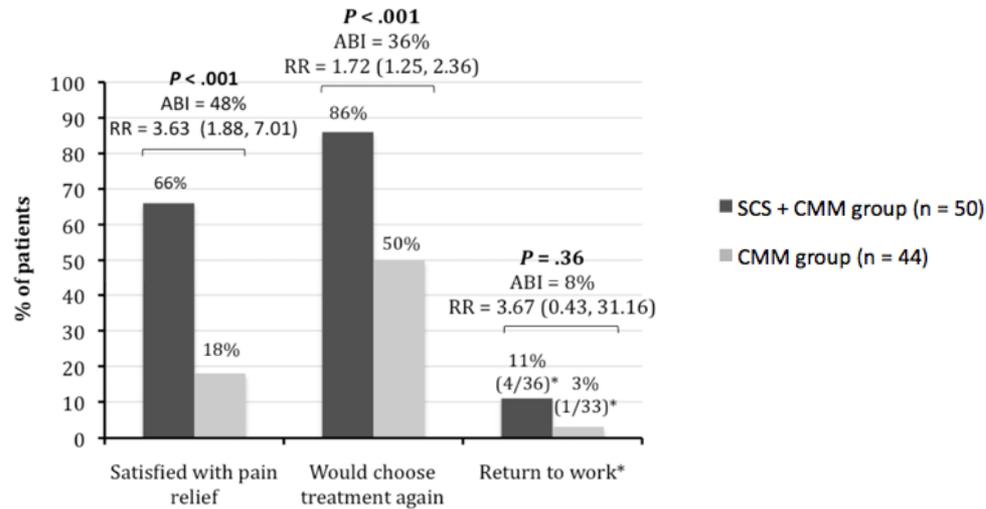
Author	Diagnosis	Treatments	Outcome measure	F/U period	Results
Kumar (2007)	FBSS	SCS + CMM vs. CMM	SF-36; EQ-5D utility scores	6 months	SCS: better scores (except role-physical subscale of SF-36: no difference)
Kemler (2000, 2004, 2008)	FBSS	SCS + PT vs. PT	% change in QoL; Nottingham Health Profile, EQ-5D, Self-Rating Depression Scale	6 & 24 months; 60 months	No differences

Efficacy– Patient satisfaction & perceived effect (1 of 2)

2 RCTs (FBSS, CRPS)



Kumar: FBSS (6 months)

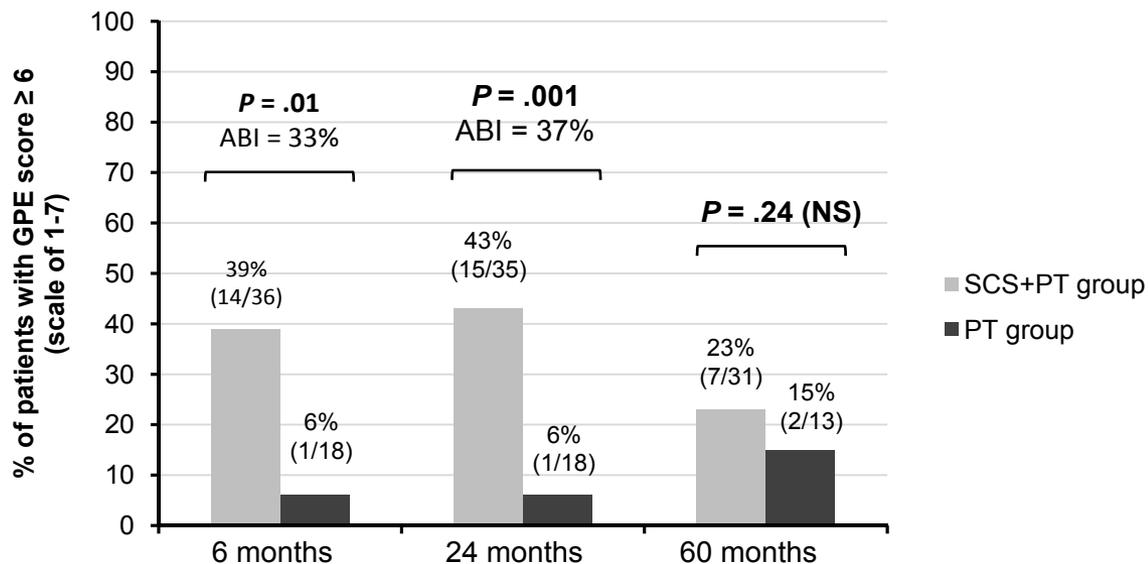


Efficacy– Patient satisfaction & perceived effect (2 of 2)



Global perceived effect (GPE)

Kemler: CRPS I (6, 24, & 60 months): % of patients who reported “much improved”

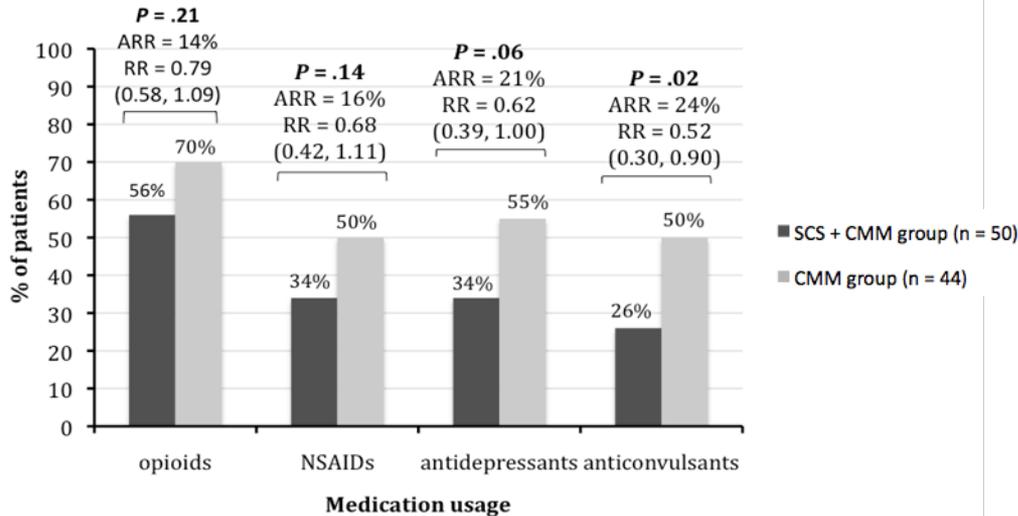




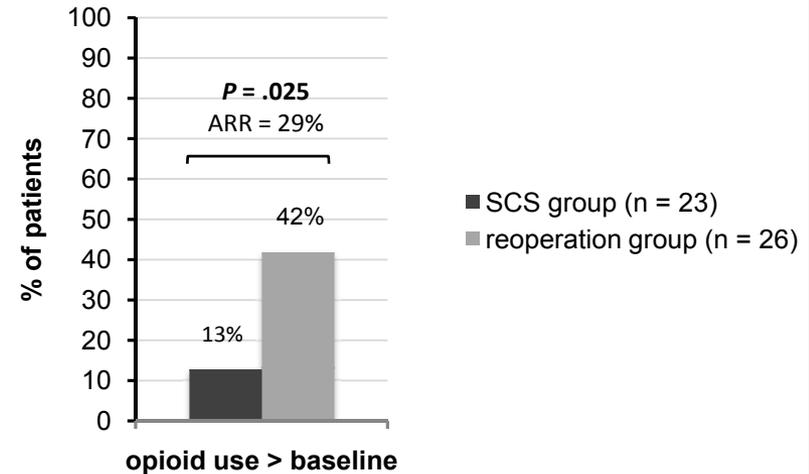
Efficacy– Medication usage

2 RCTs (FBSS)

Kumar: FBSS (6 months)



North: FBSS (2.9 ± 1.1 years)



Efficacy– Summary Strength of Evidence



Pain, perceived effect of treatment and patient satisfaction:

- *SCS is superior* to conventional therapies (CMM, physical therapy, or reoperation) in the first 2–3 years.
- This benefit in reducing pain tends to decrease after 2 to 3 years

Strength of evidence = HIGH

Efficacy– Summary Strength of Evidence



Function and quality of life:

- It is unclear whether SCS is better than conventional therapies in improving function and QoL
- One trial reports substantial improvement in both function and QoL after 6 months.
- A second trial reports no difference in function at 6 or 24 months or QoL at 6, 24 or 60 months
- A third trial reports no difference in function at a mean of 2.9 years.

Strength of evidence = LOW

Key Question 1



Effectiveness

Studies that met our inclusion criteria:

1 prospective cohort study (Turner 2010):

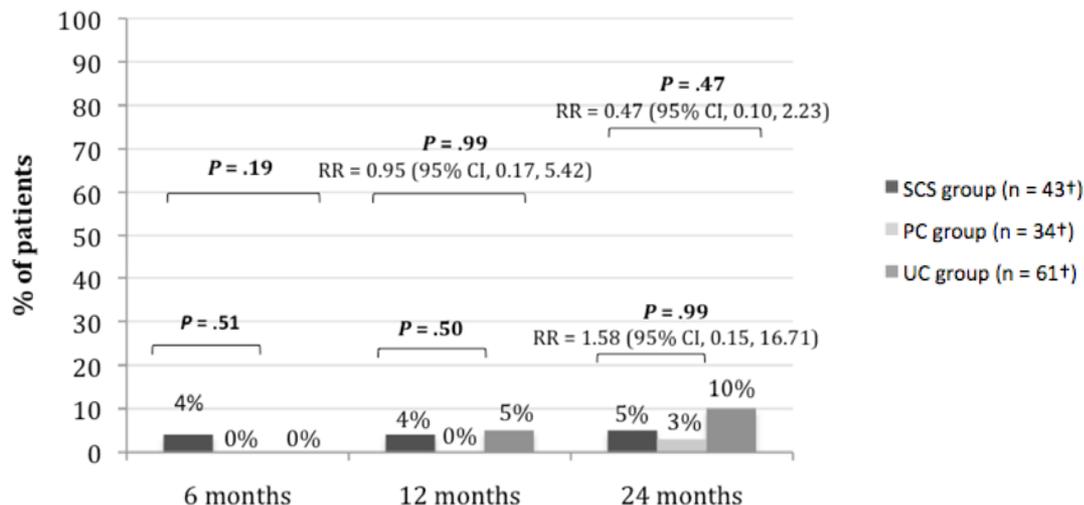
- FBSS patients receiving workers' compensation payments in the state of Washington

Effectiveness– “Success”



“Success” = leg pain relief $\geq 50\%$, RDQ improvement of ≥ 2 points, and less than daily opioid usage

Turner: FBSS (6, 12, & 24 months)



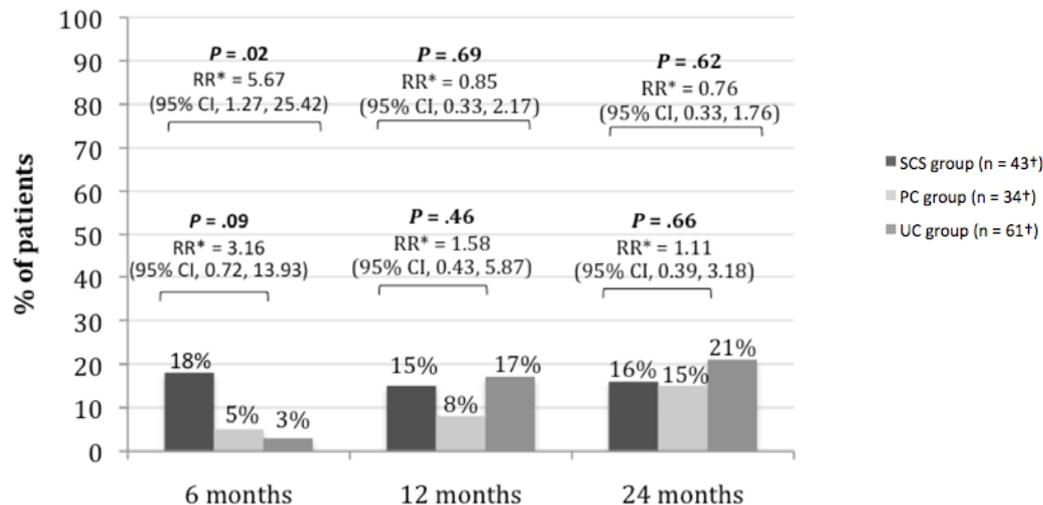
Alternate definition of “success” = leg pain relief $\geq 30\%$; RDQ improvement of ≥ 5 points, and less than daily opioid usage.

At 6 months, significantly more SCS patients achieved this outcome compared with PC (22% versus 5%; $P = .03$) and UC (22% versus 5%; $P = .01$); the differences were no longer significant by 12 or 24 months.



Effectiveness– Pain relief

Turner: FBSS (6, 12, & 24 months): leg pain relief $\geq 50\%$



Clinical meaningful difference may be pain relief $\geq 30\%$: **SIMILAR RESULTS**

Mean VAS leg pain and back pain scores were similar in all three groups at all follow-ups.

Effectiveness– other outcomes



Function:

There were **no differences** in function between treatment groups as measured by the Roland-Morris Disability Questionnaire, ability to perform tasks, work/disability status, and mean time lost from work.

HR-QoL:

There were **no differences** in mean SF-36 mental health scores between treatment groups.

Medication usage:

There were **no differences** between groups in the usage of most medications (**except anticonvulsants**, which was higher in the SCS versus PC group).

Effectiveness– Summary Strength of Evidence



In FBSS patients receiving workers' compensation payments,

- ***SCS is similar*** to conventional therapies (Pain Clinic, Usual Care) with respect to the composite score “success” in the first 2 years
- *SCS may result in better leg pain relief* compared with conventional therapies (Pain Clinic, Usual Care) in the first 6 months
- No other outcome measure (pain, function, daily opioid usage, and quality of life) were significantly different between SCS and conventional therapies in the first 2 years.

Strength of evidence = LOW

Key Question 2



What is the evidence of safety of SCS?

Safety outcomes:

1. Revision
2. Complications
3. Mortality

Key Question 2



What is the evidence of safety of SCS?

Studies that met our inclusion criteria:

3 RCTs, 1 cohort study (from Key Question 1):

- FBSS, CRPS

6 case series (follow-up \geq 5 years)

- Neuropathic pain in \geq 75% patients
- N = 36 – 338 patients per study (mean N = 158)

Revision/replacement

SoE = HIGH that revision is not uncommon following SCS



Revision/ replacement:	2 – 3 year f/u (from 3 RCTs, 1 cohort study)	≥ 5 year f/u (from 1 RCT, 6 case series)
Electrode	4 – 21% patients	3 – 34% patients 7.4% electrodes
Generator	1 – 11% patients	1 – 54% patients 5.4% generators
Entire system (replacement)	3 – 4% patients	1.2 – 6% patients
Entire system (removal)	8 – 22% patients	(% patients NR)
Overall rate	25 – 38% patients	42 – 60% patients

Other complications & side effects



	2 – 3 year f/u (from 3 RCTs, 1 cohort)	≥ 5 year f/u (from 1 RCT, 6 case series)
SCS-related	8 – 100% patients	0 – 6.5% patients
Related to trial stimulation	16% patients	NR



Mortality

SoE = HIGH that the rate of mortality due to SCS is low

No deaths were attributed to the SCS device, procedure, or implantation.

	2 – 3 year f/u (3 RCTs, 1 cohort)	≥ 5 year f/u (1 RCT, 6 case series (CS))
Death (any cause)	SCS group: 1.4% patients (2 deaths; 4 studies) Control groups: 0% patients (4 studies)	SCS group: 0% patients (1 RCT) 1.0% patients (3 CS) Control groups: 0% patients (1 RCT)

In the cohort study, one patient nearly died due to complications that resulted from the trial stimulation.

Key Question 3



Is there evidence of differential efficacy or safety issues with use of spinal cord stimulation?

Key Question 3



Studies that met our inclusion criteria:

6 prognostic studies:

- Neuropathic pain in $\geq 75\%$ patients
- Permanent SCS devices implanted in 32 – 53 patients per study

Special populations

(reported by ≥ 2 studies)



No strong evidence of differential efficacy or safety in subpopulations based on the following characteristics:

- Age
- Sex
- Workers' compensation or other disability payments
- Pain intensity, duration or location
- MMPI scores
- Number of prior surgeries



Key Question 4

What is the evidence of cost implications and cost effectiveness of spinal cord stimulation?



Economic conclusions

Two published studies, one HTA that included two independent models:

	Population	Conclusions
Taylor & Taylor	<u>FBSS</u> : SCS versus CMM	<u>2 years</u> : SCS cost-effective, but more data needed <u>Lifetime model</u> : SCS is more effective and less costly than CMM
North*	<u>FBSS</u> : SCS versus reoperation	<u>3 years</u> : SCS is more effective and less costly than reoperation
Simpson HTA (ABHI & ScHARR models)	<u>FBSS</u> : SCS versus reoperation or CMM <u>CRPS</u> : SCS versus CMM	<u>15-year model</u> : SCS is more effective and less costly than CMM

* US-based study

Economic conclusions



- At moderate (< \$20,000) ICER levels, SCS is associated with improved outcomes and increased costs compared with CMM and/or reoperation in the shorter term.
- In the longer term, SCS dominance over control treatments is less certain due to lack of efficacy evidence past 2 – 3 years.

Strength of evidence = MODERATE

Points to consider



Efficacy

On one hand...	On the other hand...
<ol style="list-style-type: none"><li data-bbox="112 525 819 639">1. We have 3 well-conducted RCTs<li data-bbox="112 733 838 925">2. Outcome measures include pain, patient satisfaction, function, and quality of life	<ol style="list-style-type: none"><li data-bbox="884 525 1367 574">1. Studies are small<li data-bbox="884 668 1781 1059">2. Heterogeneous with respect to:<ul style="list-style-type: none"><li data-bbox="904 733 1781 782">• patient population characteristics<li data-bbox="904 805 1781 853">• how key outcomes were assessed<li data-bbox="904 876 1182 925">• diagnosis<li data-bbox="904 948 1340 996">• follow-up times<li data-bbox="904 1019 1240 1068">• comparator<li data-bbox="884 1153 1781 1202">3. Industry sponsorship (2 of 3 RCTs)

Points to consider



Effectiveness

On one hand...	On the other hand...
<ol style="list-style-type: none"><li data-bbox="131 582 850 773">1. We have 1 well-conducted prospective cohort study (good internal validity)<li data-bbox="131 862 819 985">2. Conducted in a specific population (L&I patients)<li data-bbox="131 1073 923 1196">3. Composite outcome measure consistent with clinical goals	<ol style="list-style-type: none"><li data-bbox="1000 582 1711 705">1. Limited generalizability of results<li data-bbox="1000 793 1816 982">2. Composite outcome measure makes achieving success more rare<li data-bbox="1000 1071 1464 1125">3. L&I sponsorship

Points to consider



Safety

1. **Inconsistent reporting of complications, side effects and revisions**
 - **Overall rate of revision unclear**
 - **Mortality generally not described in the context of SCS**

Points to consider



Cost effectiveness

- 1. Cost effectiveness based on the 3 RCTs**
- 2. Common outcome used among studies was pain**
- 3. The conclusion of cost effectiveness in the longer term is based on efficacy assumptions that may not be accurate**

Questions?



HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective¹ as expressed by the following standards.²

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.³

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

¹ Based on Legislative mandate: See RCW 70.14.100(2).

² The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

³ The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of Evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the Evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence⁴ using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. *Factors for Consideration - Importance*

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

⁴ Based on GRADE recommendation: <http://www.gradeworkinggroup.org/FAQ/index.htm>

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
<p>CMS National Policy Decisions – WA HTA Page: 39</p> <p>Centers for Medicare and Medicaid Services</p>	1995	<p>CMS will cover the use of SCS for the relief of chronic intractable pain when all of the following conditions have been met:</p> <ul style="list-style-type: none"> - SCS implantation is only used as a late or last resort for patients with chronic intractable pain; - Patients have undergone careful physical and psychological screening by a team of physicians; - There has been a previous demonstration of pain relief with temporarily implanted electrodes; - Everything needed for the proper treatment and follow-up of the patient is available (i.e., facilities, equipment, professional and support personnel, etc); and - SCS implantation employs percutaneous insertion of electrodes into the epidural space. 	No	
<p>Guidelines – WA HTA Page: 26</p> <p><i>American Society of Anesthesiologists Task Force and the American Society of Regional Anesthesia and Pain Medicine</i></p>	2010	<p>Members and consultants “strongly agree” SCS should be used for persistent radicular pain, and all agree that it should be used for other conditions, such as postherpetic neuralgia, postamputation pain, peripheral neuropathic pain, spinal cord injury, CRPS, cauda equine syndrome and cervical root injury pain. Strongly agree that a SCS trial should be performed prior to considering permanent implantation of a stimulation device.</p>	Evidence and consensus	
<p>Guidelines – WA HTA Page: 26 & 27</p> <p><i>American Pain Society</i></p>	2009	<p>That for the treatment of persistent and disabling radicular pain following surgery for herniated disc (with no evidence of a persistently compressed nerve root), clinicians discuss the risks and benefits of SCS as a treatment option, and note the high rate of complications following SCS implantation.</p>	Evidence Classified as weak recommendation; moderate quality	
<p>Guidelines – WA HTA Page: 27</p> <p><i>Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain</i></p>	2009	<p>The recommendation for clinical use of SCS for FBSS on a long-term basis is 1B or 1C, indicating a strong recommendation in which the benefits clearly outweigh the risk and burdens.</p>	Evidence cited	

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
<p>Guidelines – WA HTA Page: 27</p> <p><i>Institute for Clinical Systems Improvement (ICSI)</i></p>	2008	<p>Regarding treatment of chronic pain, the ICSI considers placement of a SCS to be a level II treatment, which is only considered appropriate in patients who have failed more conservative (level I) treatment options (including transcutaneous nerve stimulation, drug therapies, physical rehabilitation, and behavioral techniques). SCS should be performed alongside a comprehensive treatment plan that includes pharmacological, rehabilitative, and psychological interventions; if used alone, the evidence is limited in its success.</p>	Evidence cited	
<p>Guidelines – WA HTA Page: 27</p> <p><i>National Institute for Health and Clinical Excellence (NICE)</i></p>	2008	<p>SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain of at least 50mm on a 0-100mm VAS for at least six months despite appropriate conventional medical management, and who have had a successful trial of stimulation.</p> <p>SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed.</p> <p>If different SCS systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered.</p>	Evidence cited	
<p>Guidelines – WA HTA Page: 27</p> <p><i>American College of Occupational and Environmental Medicine</i></p>	2007	<p>The use of SCS for acute, subacute, or chronic low back pain; radicular pain syndromes; or FBSS is not recommended based on insufficient evidence for an evidence-based recommendation due to high costs or high potential for harm to the patient.</p>	Evidence cited; Rated I (Insufficient or Irreconcilable)	

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
<p>Guidelines – WA HTA Page: 28</p> <p><i>European Federation of Neurological Societies (EFNS)</i></p>	2007	<p>The EFNS concluded that there was level B evidence for the effectiveness of SCS in FBSS and CRPS type 1. They also found positive evidence for SCS in the treatment of CRPS type II, peripheral nerve injury, diabetic neuropathy, post-herpetic neuralgia, brachial plexus lesion, stump pain, phantom limb pain, and partial spinal cord injury, but require confirmatory comparative trials for the unreserved recommendation of SCS use in these conditions.</p>	Evidence cited; Rated level B, probably effective	
<p>Guidelines – WA HTA Page: 28</p> <p><i>Reflex Sympathetic Dystrophy Syndrome Association (RSDSA)</i></p>	2006	<p>CRPS patients who are not progressing in the functional restoration/interdisciplinary algorithm to proceed in a stepwise progression from minimally invasive therapies (sympathetic nerve blocks, intravenous regional nerve blocks, and somatic nerve blocks) to more invasive therapies (neurostimulation, epidural and plexus catheter blocks(s), and Intrathecal drug infusion), and finally to surgical and experimental therapies (sympathectomy and motor cortex stimulation) in order to facilitate the patient's functional improvement and pain control.</p>		
<p>Guidelines – WA HTA Page: 28</p> <p><i>Evidence-based clinical practice guidelines</i></p>	2005	<p>Despite growing number of studies and systematic reviews regarding the efficacy of SCS, the current guidelines do not recommend their use in chronic non-malignant pain syndrome patients given the continued absence of quality research.</p>	Evidence cited	

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Spinal Cord Stimulation	
Safety Outcomes	Safety Evidence
Mortality	
Morbidity	
Revision and removal rates	
Infections	
Lead Migrations; other technical defects	
Other adverse events	
Efficacy – Effectiveness Outcomes	Efficacy / Effectiveness Evidence
Pain Relief <ul style="list-style-type: none"> - Short term - Med term - Long term 	
Functional improvement <ul style="list-style-type: none"> - Short term - Med/long term 	
Quality of Life <ul style="list-style-type: none"> - Short term - Med/long term 	
Pain medication usage	
Return to work	
Duration and intensity of use	
Other Patient outcomes	
Special Population / Considerations Outcomes	Special Population Evidence
Cost	Cost Evidence
Cost Implications	

Cost Effectiveness	

Clinical Committee Evidence Votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote

Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

_____ Not Covered. _____ Covered Unconditionally. _____ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

- 1) Does the committee have enough information to identify conditions or criteria?
 - Refer to evidence identification document and discussion.
 - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
 - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
- 2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
 - What are the known conditions/criteria and evidence state
 - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
 - Direct outcome or surrogate measure
 - Short term or long term effect
 - Magnitude of effect
 - Impact on pain, functional restoration, quality of life
 - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
 - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
 - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
 - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?