EVIDENCE-BASED GUIDELINES

Spinal Cord Stimulator

The Rand Institute for Civil Justice and Rand Health has published a document at the request of the State of California in 2005. This document is available from www.Rand.org. The title of the document is "Evaluating Medical Treatment Guideline Sets for Injured Workers in California". The five guideline sets that met all their screening criteria include:

1.	AAOS	Clinical Guidelines by the American Academy of Orthopedic Surgeons.
2.	ACOEM	American College of Occupational and Environmental Medicine Occupational Medicine Practice Guidelines.
3.	Intracorp	Optimal Treatment Guidelines, part of Intracorp Clinical Guidelines Tool
4.	McKesson	McKesson/InterQual Care Management Criteria and Clinical Evidence Summaries.
5.	ODG	Official Disability Guidelines: Treatment in Workers Compensation by Work-Loss Data Institute.

A multidisciplinary clinical panel evaluated the guideline content, and 11 clinicians were selected from national specialty societies. They were national experts that were practicing at least 20% of the time and who had experience in treating injured workers. Each guideline had its strengths and weaknesses. These are summarized in the document. There were some panelists that reported preferring the "specialty" society guidelines to the five guideline sets that they reviewed. The conclusion of the clinical content evaluation is as follows:

1. All five guideline sets appear far less than ideal and barely meet standards.
2. The clinical panel preferred the ACOEM Guidelines to the alternatives, but they were not comprehensive in the entire content rating.
3. ACOEM Guidelines had surgical weakness specifically as it relates to lumbar spinal fusion, which was well addressed in the AAOS Guideline sets.

Short-term recommendations were as follows:

4. The ACOEM Guidelines were preferred, and there was no reason to switch to a different comprehensive guideline set.
5. California can confidently implement the ACOEM Guidelines for carpal tunnel surgery, shoulder surgery, and lumbar spinal decompression surgery.
6. For spinal fusion surgery the AAOS Guidelines should be followed.
7. Other surgical topics could be implemented utilizing the ACOEM Guidelines.

8. The validity of the ACOEM Guidelines for physical modalities remains uncertain, and they are **not confident** that the ACOEM Guidelines are valid for non-surgical topics.
9. The stakeholder interview suggested that acupuncture, **chronic conditions**, and other topics may not be covered well by the ACOEM Guidelines.
10. For topics to which the adopted guidelines (ACOEM) do not apply, the State should clarify who bears the burden of proof for establishing appropriateness of care.
11. Because medical literature addressing the appropriateness and quantity of care may be limited for some physical modalities and other tests, as well as therapies, some guideline content will include a component of **expert opinion**. Therefore, the State should clarify whether expert opinion constitutes an acceptable form of evidence within "evidence-based, peer-reviewed, nationally recognized standards of care".
12. The stakeholder interview suggested that payers are **uncertain** whether they have the authority to approve exceptions to the guidelines for patients with unusual medical needs. Therefore, the State should consider specifically authorizing payers to use **medical judgment** in decided whether care at variance with the adopted guidelines should be allowed.

The ACOEM Guidelines do not provide any guidance whatsoever regarding epidural stimulation. Therefore, I will now refer to the Official Disability Guidelines (ODG) as it relates to spinal cord stimulators. A review of the guidelines clearly states that they are recommended only for **selected** patients in cases where **less invasive procedures have failed or are contraindicated** and the following indications for stimulator implantation exist:

1. Failed back syndrome.
2. Complex regional pain syndrome.
3. Post-amputation pain.
4. Post-herpetic neuralgia.
5. Spinal cord injury.
6. Multiple sclerosis.
7. Peripheral vascular disease.

A review of the Medical Policy of Blue Cross of California regarding implanted spinal cord stimulators, policy number SURG.00060, effective date 05/07/2007, reveals the following policy statement:

> A temporarily implanted spinal cord stimulator for the treatment of chronic (greater than six months' duration) intractable neuropathic pain is considered **medically necessary** when **all** the following criteria are met:
>
> 1. Documentation in the medical record of failure of six months of conservative treatment modalities. (This patient exceeds that limit.)

2. Further surgical intervention is not indicated. Comment: This patient is not a surgical candidate for any type of corrective measure.
3. Psychological evaluation has been obtained, and the evaluation unequivocally states the patient is not psychologic in origin and benefit would occur with implantation.
4. No contraindication to implantation exists, such as sepsis or coagulopathy.
5. Objective documentation of pathology in the medical record.

A permanently implanted spinal cord stimulator for the treatment of chronic (greater than six months' duration) intractable neuropathic pain is considered **medically necessary** when a temporary trial of spinal cord stimulation has been successful. Successful is defined as:

1. Fifty percent reduction in pain for at least two days.
2. Improvement in function documented in the medical record.

The New England Journal of Medicine, volume 343, number 9, August 31, 2000, has an article, "Spinal Cord Stimulation in Patients with Chronic Reflex Sympathetic Dystrophy" on page 618. It is a randomized trial involving patients who have had reflex sympathetic dystrophy for at least six months. Thirty-six patients were assigned to receive treatment with spinal cord stimulation plus physical therapy, and 18 were assigned to receive physical therapy alone. Of the 36 patients test stimulation was successful in 24 patients. The other 12 patients did not receive implanted stimulators. Results were evaluated at one month, three months, and again at six months. Of the 36 patients assigned to receive stimulation and physical therapy, 14 patients had a score of 6 with a global perceived effect (benefit) as compared to 1 of 18 patients that received physical therapy alone. Spinal cord stimulation was successful in 20 of 36 patients. Fourteen had a score of 6 for the global perceived effect. Eighteen had a Visual Analog score that was at least 50% lower than the baseline score. Fourteen of the 24 patients who received spinal cord stimulation (58%) had a "much improved" Visual Analog score for the global perceived effect as compared to 1 of 18 patients that received physical therapy alone. The conclusion was that functional status did not improve in either group of patients; however, the reason given was that possibly spinal cord stimulation treats pain, but not the disease itself. Consequently, a reduction in pain is not accompanied by an improvement in function; however, the treatment results in an important over-all improvement.

It is very clear after a review of the ODG, Blue Cross, and the New England Journal of Medicine article, and the lack of pharmacological response by this patient that a trial of epidural stimulation should occur. The ODG recommend a psychological clearance prior to the trial. I will seek authorization for psychological clearance on this patient's behalf and afterwards seek authorization for an epidural stimulation trial should the patient be psychologically cleared.

Specialty-specific guidelines provide even better substantial medical evidence regarding spinal cord stimulation. In the Pain Physician year 2003, volume 6, pages 3-81, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. In that paper on pages 41

through 43 there has been an excellent publication of the current information available regarding the evidence-based guidelines of neuromodulation (epidural steroidal) which will be provided in its entirety in this Discussion section:

Present-day spinal cord stimulation (SCS) began shortly after Melzak and Wall proposed the gate control theory in 1965 (1110). As a direct result of this theory, in 1967, Shealy et al (1111) implanted the first spinal cord stimulator device for the treatment of chronic pain. Over the course of the last 35 years, advancements in basic science research, and technology have led spinal cord stimulation to be an accepted, reliable treatment for many neuropathic and/or vascular insufficiency pain states (1112).

The mechanism of action of spinal cord stimulation is not completely understood. However, recent research has given us insight into effects occurring at the local and supraspinal levels, and through dorsal horn interneuron and neurochemical mechanisms (1113, 1114). It is interesting to note that, in light of recent findings, the theory that inspired Shealy et al (1111) to pursue spinal cord stimulation for chronic pain, may, in fact, have little relevance to its actual effect.

Despite what is known about the mechanism of action of SCS and the outcomes of many studies, much confusion remains regarding the indications for SCS. A comprehensive review of the literature demonstrates positive results in neuropathic and vascular insufficiency pain states (1114, 1115). There is, however, no credible evidence to support the use of SCS in primarily nociceptive pain conditions (degenerative disk disease, sacroiliac dysfunction, arthritis, cancer, and acute tissue injury). In fact, studies using empirical and computer modeling (1112, 1116) and those looking at the effects of SCS in animals (1117) and in man (1118) have demonstrated no significant effect on nociception at clinical relevant stimulation parameters.

In critical review of the available SCS literature, consideration must be given to the fact that most fall within the level IV (limited) or level V (indeterminate) categories out of necessity due to the invasiveness of the modality and inability to provided blinded treatment as well as other constraints noted in the introduction of this text. Recognition must also be given to the time frame within which a study was performed due to rapidly evolving SCS technology. Basic science knowledge, implantation techniques, lead placement locations, contact array designs, and programming capabilities have changed dramatically from the time of Shealy et al (1111). These improvements have led to decreased morbidity and much greater probability of obtaining adequate paresthesia coverage with subsequent improved outcomes (1119).

In the United States, the primary indications for spinal cord stimulation are failed back surgery syndrome and complex regional pain syndromes type I and type II (1120). However, in Europe, most interest in spinal cord stimulation has been in the treatment of chronic intractable angina and pain and disability due to peripheral vascular disease (1120).

There have been two systematic literature syntheses. The first, by Turner et al (28) from the articles related to the treatment of failed back surgery syndrome by spinal cord stimulation, from 1966 to 1994. They reviewed 39 studies that met the inclusion criteria. The mean follow-up period was 16 months with range of 1 to 45 months. Pain relief exceeding 50% was experienced

by 59% of patients with a range of 15% to 100%. Complications occurred in 42% of patients, with 30% of patients experiencing one or more stimulator-related complications. However, all the studies were case-controlled investigations. Based on this review, the authors concluded that there was insufficient evidence from the literature for drawing conclusions about the effectiveness of spinal cord stimulation relative to no treatment or other treatments, or about the effects of spinal cord stimulation on patient work status, functional disability, and medicine use.

The second, by North and Wetzel (1120) consisted of a review of case control studies and two prospective control studies. They concluded that if a patient reports a reduction in pain of at least 50% during a trial, as determined by standard rating methods, and demonstrates improved or stable analgesic requirements and activity levels, significant benefit may be realized from a permanent implant. A note of caution by the authors, similar to that raised by Turner et al (28), was that although the bulk of the literature appears to support a role for spinal cord stimulation, primarily in neuropathically driven pain syndromes, the quality of the literature must be considered as it is overwhelmingly empiric. North and Wetzel (1120) concluded that on the basis of the current evidence, spinal cord stimulation may represent a valuable treatment option, particularly for patients with chronic pain of predominantly neuropathic origin and topographical distribution involving the extremities. They also added that the potential treatment of other pain topographies and etiologies by spinal cord stimulation continues to be studied.

There have been two randomized controlled trials evaluating the effectiveness of spinal cord stimulation. Of these, one randomized controlled trial evaluated effectiveness of spinal cord stimulation in chronic spinal pain (1121), whereas the second study involved evaluation of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy (1122). In addition, there have been two prospective trials (1123, 1124). Further, in the field of spinal cord stimulation as with other interventional techniques in chronic spinal pain management, there are numerous retrospective studies that promote the efficacy of spinal cord stimulation. These studies range in long-term efficacy from approximately 12% to greater than 90% (1125-1139).

Kemler et al (1122) reported the results of a randomized trial involving patients who carried a diagnosis of CRPS for at least six months. In this study, 36 patients were assigned to receive a standardized physical therapy program together with spinal cord stimulation, whereas 18 patients were assigned to receive therapy alone. In all cases, the CRPS involved the upper extremities, and all the patients underwent a percutaneous trial of at least 7 days duration. In 24 of the 36 patients, randomized to spinal cord stimulation, along with physical therapy, the trial was successful, and permanent implantation was performed. At a 6-month follow-up assessment, the patients in the spinal cord stimulation group had a significantly greater reduction in pain, and a significantly higher percentage were graded as much as improved for the global perceived effect. The authors concluded that in short-term, spinal cord stimulation can reduce pain and improve the quality of life for patients with CRPS involving the upper extremities.

North et al (1121) selected 50 patients as candidates for repeat laminectomy. All the patients had undergone previous surgery, and were excluded from randomization if they presented with severe spinal canal stenosis, extremely large disc fragments, a major neurological deficit such as foot drop, or radiographic evidence of gross instability. In addition, patients were excluded for

untreated dependency on narcotic analgesics or benzodiazepines, major psychotic comorbidity, the presence of any significant or disabling chronic pain problem, or a chief complaint of low back pain exceeding lower extremity pain. This was a preliminary report. Crossover between groups was permitted. The 6-month follow-up report included 27 patients. At this point they became eligible for crossover. Of the 15 patients who had undergone re-operation, 67% (10 patients) crossed over to SCS. Of the 12 who had undergone SCS, 17% (2 patients) opted for crossover to re-operation. Additionally, of the 19 patients who reached their 6-month follow-up assessment after re-operation, 42% (8 patients) opted for spinal cord stimulation outside the study. For 90% of the patients, long-term (3-year follow-up) evaluation has shown that spinal cord stimulation continues to be more effective than re-operation, with significantly better outcomes by standard measures and significantly lower rates of crossover to the alternate procedure. Additionally, patients randomized to re-operation used significantly more opiate analgesics than those randomized to spinal cord stimulation. Other measures assessing activities of daily living and work status did not differ significantly. The major disadvantage of this randomized trial is that the long-term results are unpublished at the present time and are reported by authors in review (1130).

Two recent, prospective case studies have been done. The first, by Barolat et al (1124) examined the outcomes of patients with intractable low-back pain treated with epidural spinal cord stimulation (SCS) utilizing paddle electrodes and a radio frequency (RF) stimulator. The study was designed to collect data from 60 patients at four centers and examine their outcomes at, or up to two years post implantation. A total of 44 patients were implanted. The majority of patients reported fair to excellent pain relief in both the low back and legs. At 6 months 91.6% of the patients reported fair to excellent relief in the legs, and 82.7% of the patients reported fair to excellent relief in the low back. At 1-year 88.2% of the patients reported fair to excellent relief in the legs, and 68.8% of the patients reported fair to excellent relief in the low back. Significant improvement in function and quality of life was found at both the 6-month and 1-year follow-ups using the Oswestry and SIP respectively. The majority of patients reported that the procedure was worthwhile (92% at 6-months, 88% at 1-year). No patient indicated that the procedure was not worthwhile. The authors concluded that the SCS proved beneficial at one year for the treatment of patients with chronic low back and leg pain.

The second, by Burchiel et al (1123) in 1996 published the results of a multi-center prospective study investigating spinal cord stimulation. The study included 182 patients with a permanent system after a percutaneous trial. Patient evaluation of pain and functional levels was performed before implantation, then 3, 6, and 12 months after implantation. A 1-year follow-up evaluation was available for 70 patients. Pain and quality-of-life measures showed statistically significant improvement during the treatment year. Complications requiring surgical interventions were experienced by 17% (12 of 70) of the patients. Medication usage and work status were not changed significantly.

Cost Effectiveness: Cost effectiveness of spinal cord stimulation was evaluated by Kumar et al (1140). They prospectively followed 104 patients with failed back surgery syndrome. Of the 104 patients, 60 were implanted with a spinal cord stimulation using a standard selection criterion. Both groups were monitored over a period of 5 years. The stimulation group annual cost was

$29,123 versus $38,029 in the control group. The authors found 15% return to work in the stimulation group versus 0% in the control group. The higher costs were in the categories of medications, emergency center visits, x-rays, and ongoing physician visits.

Bell et al (1141) performed an analysis of the medical costs of spinal cord stimulation (SCS) therapy in the treatment of patients with failed back surgery syndrome (FBSS). The medical costs of SCS therapy were compared with an alternative regimen of surgeries and other interventions. Externally powered (external) and fully internalized (internal) SCS systems were considered separately. No value was placed on pain relief or improvements in the quality of life that successful SCS therapy can generate. The authors concluded that by reducing the demand for medical care by FBSS patients, SCS therapy can lower medical costs and found that, on average, SCS therapy pays for itself within 5.5 years. For those patients for whom SCS therapy is clinically efficacious, the therapy pays for itself within 2.1 years.

Kemler and Furnee (1142) performed a similar study but looking at "chronic reflex sympathetic dystrophy (RSD)" using outcomes and costs of care before and after the start of treatment. Fifty-four patients with chronic RSD were randomized to receive either SCS together with physical therapy (SCS+PT; n=36) or physical therapy alone (PT;n=18). Twenty-four SCS+PT patients responded positively to trial stimulation and underwent SCS implantation. During 12 months of follow-up, costs (routine RSD costs, SCS costs, out-of-pocket costs) and effects (pain relief by Visual Analog scale, health-related quality of life (HRQL) improvement by EQ-5D) were assessed in both groups. Analyses were carried out up to 1 year and up to the expected time of death. SCS was both more effective and less costly than the standard treatment protocol. As a result of high initial costs of SCS, in the first year, the treatment per patient is $4,000 more than control therapy. However, in the lifetime analysis, SCS per patient is $60,000 cheaper than control therapy. The authors found SCS to be both more effective and less expensive as compared with the standard treatment protocol for chronic RSD.

Summary of Evidence: Spinal cord stimulation is an invasive, interventional surgical procedure. The evidence included one randomized trial (1121), two prospective trials (1123, 1124) and multiple retrospective trials. **The evidence for spinal cord stimulation in properly selected population with neuropathic pain is moderate for long-term relief.**

Complications: Complications with spinal cord stimulation range from simple, easily correctable problems, such as lack of appropriate paraesthesia coverage, to devastating complications such as paralysis, nerve injury, and death.

North et al (1119) in 1993 reported their experience in 320 consecutive patients treated with SCS between 1972 and 1990. A 5% rate of subcutaneous infection was seen and is consistent with the literature. The predominant complication consisted of lead migration or breakage. In an earlier series, bipolar leads required electrode revision in 23% of patients. The revision rate for patients with multichannel devices was 16%. Failure of the electrode lead was observed in 13% of patients and steadily declined over the course of the study. When analyzed by implant type (single-channel percutaneous, single-channel laminectomy, and multichannel), the lead migration rate for multichannel devices was approximately 7%. Analysis of hardware reliability

for 298 permanent implants showed that technical failures (particularly electrode migration and malposition) and clinical failures had become significantly less common as implants had evolved into programmable, "multichannel" devices. North and Wetzel (1120), in the literature review, reported that complication rates have declined to approximately 8%, and re-operation is necessary in approximately 4% of patients. They also reported that when current percutaneous techniques are used, a lead migration rate lower than 3% may be achieved.

More recent studies by Barolat et al (1124) and May et al (1143) reported lead revision rates due to lead migration of 4.5% and 13.6% and breakage of 0% and 13.6% respectively. Infections occurred in 7% and 2.5% of cases respectively. No serious complications wee seen in either study. These three studies are representative of the majority of recent studies and are an accurate reflection of present state of the art SCS therapy.

Infections range from simple infections at the surface of the wound to epidural abscess. The reported incidence of abscess is extremely rare, and no reports associated with SCS were found. In review of the literature regarding temporary epidural catheters, Sarubbi et al (1144) discovered only 20 well-described cases. The mean age of these 22 patients was 49.9 years, the median duration of epidural catheter use was 3 days, and the median time to onset of clinical symptoms after catheter placement was 5 days. The majority of patients (63.6%) had major neurological deficits, and 22.7% also had concomitant meningitis.

UPDATED 2009 CHRONIC PAIN MEDICAL TREATMENT GUIDELINES

Chronic Pain Medical Treatment Guidelines 8 C.C.R. §§9792.20 – 39792.26 MTUS (Effective July 18, 2009)

Spinal cord stimulators (SCS)

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004) See indications list below. See Complete list of SCS_References. This supporting evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. (Sundaraj, 2005) Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There

are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. (Furlan-Cochrane, 2004) These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS and CRPS. (Taylor, 2005) (Taylor, 2006) SCS for treatment of chronic nonmalignant pain, including FBSS, has demonstrated a 74% long-term success rate (Kumar, 2006). SCS for treatment of failed back surgery syndrome (FBSS) reported better effectiveness compared to reoperation (North, 2005). A cost utility analysis of SCS versus reoperation for FBSS based on this RCT concluded that SCS was less expensive and more effective than reoperation, and should be the initial therapy of choice. Should SCS fail, reoperation is unlikely to succeed. (North, 2007) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (Taylor, 2006) SCS appears to be an effective therapy in the management of patients with CRPS. (Kemler, 2004) (Kemler, 2000) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) Neuromodulation may be successfully applied in the treatment of visceral pain, a common form of pain when internal organs are damaged or injured, if more traditional analgesic treatments have been unsuccessful. (Kapural, 2006) (Prager, 2007) A recent RCT of 100 failed back surgery syndrome patients randomized to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group), found that 48% of SCS patients versus 9% of CMM patients achieved the primary outcome of 50% or more pain relief at 6 months. This study, funded by Medtronic, suggested that FBSS patients randomized to spinal cord stimulation had 9 times the odds of achieving the primary end point. (Kumar, 2007) According to the European Federation of Neurological Societies (EFNS), spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) type I (level B recommendation). (Cruccu, 2007) The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). (NICE, 2008) PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for

the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008)

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