



**Medical Services Review Board
October 23, 2008
Minutes**

Members Present:

Beth Baker, M.D.
Barbara Baum, MS PT
Jeffrey Bonsell, D.C.
Sharon Ellis, R. N.
Barb Gibson, M.D.
Michael Goertz, M.D.
Gregory Hynan, D.C.
Robin Peterson, PT
Reed Pollack
Elizabeth Shogren, R.N.

Members Excused:

Philip Bachman, M.D.
Rose Hatmaker
Andrew Schmidt, M.D.
Jon Talsness, M.D.
Andrea Trimble Hart

Members Absent:

Kathi Hendrickson, R.N.
Charles Hipp, M.D.

Staff:

Kate Berger
Penny Grev
Julie Klejewski
William Lohman, M.D.
Patricia Todd
Lisa Wichterman
Jana Williams

Visitors:

Marge Bigelow, MAPS
Carolyn Blodgett, SFM
Natalie Haefner, WCRA
Becky Schierman, MMA
Erin Sexton, Medtronic
Mike Gonzales, Abbott Lab's

The meeting was called to order by Chairperson Beth Baker at 4:08 p.m. A quorum was present. Members and staff introduced themselves.

Approval of the April 17, 2008, Minutes

Barbara Baum made a motion to approve the April 17, 2008, minutes as presented. Sharon Ellis seconded the motion. All voted in favor of the motion and it passed.

Assistant Commissioner Announcements and Update

Patricia Todd, Assistant Commissioner, gave an update on the Worker's Compensation Unit working with external stakeholders in various work groups. They have been meeting over the spring, summer and fall on proposals for the upcoming legislative session. The work groups plan to have their recommendations to the WCAC at their next meeting sometime the end of November.

Summaries from the meetings of these work groups are available online at http://www.doli.state.mn.us/wcac_workgroups.html.

Final Review of Proposed Rules

Dr. Lohman began and led the discussion on the proposed rules for amendments to the treatment parameters and PPD schedule. All should have received the Notice regarding changes to both. Lohman reported they are in draft form and changes are still needed. Members will be continually updated on the rulemaking progress and procedures.

1. Treatment Parameters:

After the last MSRB meeting we had a recommendation from Robin Peterson to open up a dialog with the Physical Therapy Association about the use and characterization of Functional Capacity Evaluations. Current Treatment Parameters limit Functional Capacity Evaluations to one per claim for low back injuries and upper extremity disorders. Inadvertently that limitation was left out in the parameters for neck and thoracic pain. First recommendation is to add the same recommendations into the neck and thoracic parameters that already exist in the low back and upper extremity.

There is also a need to distinguish between "full scale FCE" and "comprehensive FCE" and the various other types of functional testing. The comprehensive functional capacity assessment or evaluation is an individualized examination and evaluation that objectively measures the patient's current level of function and be able to perform functional work related tasks and predicts the potential to sustain these tasks over time. DLI recommends that the Board accept this recommendation as a clarification of what was intended by this rule.

Motion by Baum to accept recommendation, seconded by Goertz. All voted in favor. Motion passed.

Lohman explained the next comment on the proposed rules on FCEs. The proposed language clarifies that it is the Comprehensive FCE that is not indicated during initial non-surgical management and other kinds of FCEs are allowed in specific circumstances.

Motion by Baum to accept recommendation, seconded by Gibson. All voted in favor. Motion passed.

Lohman explained the only other comment received objected to limiting the number of comprehensive FCEs to one per claim, and included some examples in which perhaps more than one FCE might be needed. The department's analysis of those examples indicated they would all be covered by available departures in the treatment parameters so there was no need to remove the restriction on comprehensive FCEs to one per claim. The department recommends no action.

A summary of the comments received and action taken related to FCEs is shown in the attached tables.

2. PPD Schedule:

Lohman stated a few drafting changes have occurred on page 15 and he pointed them out to the members. He then began to review the first comment received, which was on the definition of radicular pain. The current definition does not include a requirement that radicular pain be present at MMI and the department is recommending no action. After much discussion, it was agreed to defer this issue to a future date.

Lohman moved ahead to the first of several comments received on the proposed language for RSD. He explained why DLI is proposing amendments to the RSD rating, and stated the current proposed draft language was previously reviewed and approved by the board. The department recommends no action, therefore leaving the proposed language written as is. There was a lot of discussion held between the members on this issue.

A motion was made by Bonsell to approve the change as submitted by the department, which was previously approved by the board; seconded by Gibson. After more discussion a vote was called: 4 yes, no opposed, and 4 abstentions; the motion passed.

Lohman reviewed the rest of the comments received and actions taken regarding RSD as shown in the attached tables. There was no further discussion on this issue.

Lohman moved on to a comment received regarding malleolar fractures (see pages 22-23 of the proposed rule), as shown in the attached tables. The comment recommended reverting to the original language to resolve problems raised by the proposed changes. The department recommended reverting to the original language.

Motion by Shogren to accept the department's recommendation to revert back to the original rule, seconded by Baum. All voted in favor. Motion passed.

Lohman continued addressing the rest of the comments received, as shown in the attached tables, and suggested all of them be placed on future meeting agendas for discussion and possible recommendations by the Board for another round of changes to the ppd schedule. All members agreed with no formal vote.

Lohman pointed members to the "Statement of Need and Reasonableness" page in their packet. The legislature has determined that the Department, in its Statement of Need and Reasonableness for proposed rules, must evaluate the fiscal impacts of rule changes in the seven categories listed. As part of that process the department is asking all board members or anyone in the audience that has any information, comments or input on the fiscal impact of either the Treatment Parameters Rules or the PPD Schedule Rules changes to contact us with that information so we can incorporate it into our fiscal analysis. He noted DLI is also reaching out to the Insurer's Task Force and other stakeholders.

3. Final Report on Spinal Cord Stimulators:

Motion by Shogren to accept the report, seconded by Baum. All voted in favor. Motion passed.

Goertz complemented Lohman and stated this report is excellent work. Lohman continued the discussion with comments received on the proposed rules for spinal cord stimulators as shown in the attached tables. The first comment dealt with the psychiatric review required by the proposed rules. There was substantial discussion with no recommendation from the Board to change the proposed language.

Meeting Conclusion:

There was discussion on the topic issues for 2009 which include the ppd issues identified for future action and treatment parameter issues including injections, varieties of TENS units, varieties of traction devices, and laser therapy. It was then suggested that at the January meeting members talk about strategizing their priorities for the year. Come up with a top ten list of topics for the board to review. Lohman added he still has the literature review on Intrathecal Drug Delivery Systems and the final pieces of the Long Term Opiate rule to complete and present.

Todd recognized and thanked Sharon Ellis for all her work with the MSRB. This is her last meeting as she is retiring.

Motion to adjourn by Baum and Bonsell seconded. All voted in favor. Meeting adjourned at 5:56 p.m.

Respectfully submitted,

Julie Klejewski

Julie Klejewski
Executive Secretary

Attachment 1:

MSRB Meeting 10-23-08

Comments Received and Actions Taken Re: Proposed Rules for Amendments to Treatment Parameters

08-21-08 Draft	Comment	Action Taken
p. 11, 14, 17, 21	Distinguish between "full scale" FCE and various other types of testing that may be labeled FCE	<i>Accept 8-21-08 draft language; the original provisions were aimed at limiting "comprehensive FCE" not other types of testing.</i>
p. 11, 14, 17, 21	Do not limit more restricted functional testing that might be done as part of an active exercise program or a work hardening program.	<i>Accept 8-21-08 draft language; these other types of treatment are already governed by specific treatment parameters.</i>
p. 11, 14, 17, 21	Do not limit the number of comprehensive FCEs that may be done on the same injury	<i>No action; in the instances cited additional FCEs could be authorized as a departure.</i>

Attachment 2:

MSRB Meeting 10-23-08
Comments Received and Actions Taken Re: Proposed Rules for Amendments to PPD Schedule

10-15-08 Draft	Comment	Actions Taken
p. 1	Include a requirement in the definition that radicular pain be present at MMI	<i>No action; this is a medical definition. The change would be inconsistent with current case law. Discuss as part of a future round of amendments to the schedule.</i>
p. 1	Continue to include in the definition that radicular pain is characterized by consistent findings on provocation testing.	<i>No action; consistent findings on provocation testing is not considered a necessary component of the definition.</i>
p. 9	Clarify that radicular pain means symptoms “below the knee”	<i>No action; this is not true of all lumbar radiculopathies (e.g. L1 or L2).</i>
pp. 15	Do not eliminate the diagnostic criteria for RSD; removing the criteria will generate confusion and litigation and thus increase costs.	<i>Approved the 10-15-08 draft language; the WCCA has ruled repeatedly that application of this category cannot be limited by the diagnostic criteria.</i>
pp. 15	Substitute the IASP definition for RSD for the current definition	<i>No action.</i>
pp. 15	Distinguish between CRPS type I and type II; keep diagnostic criteria for type 1	<i>No action.</i>
pp. 15	Removing diagnostic criteria means that ppd will be based solely on examination findings	<i>No action; this is how ppd is determined for all other injuries.</i>
pp. 15	Since the “injury” in RSD is not to the anatomic structures or physiological systems covered in the cross references, any limitations due to RSD would be unratable.	<i>No action; the ppd schedule does not require that the injury be to the rated member but that the injury result in impairment to the rated member. While most often both the injury and the impairment are to the same member this is not always necessarily the case. E.G. a variety of injuries and conditions besides damage to the joint can lead to ratable impairment for loss of range of motion.</i>
pp. 15	Many of the cross references require that there be “organic disease or anatomical loss”; RSD is not an organic disease of these structures or systems and so could not be rated under these categories.	<i>No action; the schedule requires that there be organic disease and RSD is an organic disease that affects these structures or systems even if it is not solely or directly a disease of the system.</i>
p. 22-23	All medial malleolar fractures are intra-articular, so the distinction is irrelevant. The only true intra-articular fractures of the lateral malleolus are the type A fractures of the very tip, which are minor injuries that are ignored. Lateral malleolar fractures which cause disability are not intra-articular.	<i>Approved reverting to original rule language.</i>

p. 22-23	The schedule does not recognize fractures of the posterior malleolus, which can be a significant source of disability.	<i>Discuss as part of a future round of amendments to the schedule.</i>
Not in draft rules	Change 5223.0370 subpart 3 to eliminate the use of range of motion as a criteria for ppd	<i>Discuss as part of a future round of amendments to the schedule.</i>
Not in draft rules	Change 5223.0370 subpart 3 B to require abnormality in active range of motion instead of passive range of motion	<i>Discuss as part of a future round of amendments to the schedule.</i>
Not in draft rules	Change 5223.0370 to require that radiographic abnormalities used in rating ppd "be reasonably related to the injury or the patient's symptoms".	<i>Discuss as part of a future round of amendments to the schedule.</i>
Not in draft rules	Reduce the rating provided under 5223.0470 subpart 2 A (4) for arthroplasty of the 1 st CMC joint.	<i>Discuss as part of a future round of amendments to the schedule</i>

Attachment 3:

MSRB Meeting 10/23/08
Comments Received and Actions Taken Re: Proposed Rules for Spinal Cord Stimulators

	Comment	Actions Taken
p. 1 l. 31	What are the psychological contraindications?	<i>No change. While guidelines state that "evident unresolved major psychiatric comorbidity" is a contraindication, specific disorders are not identified in the guidelines. This is a clinical judgment made on an individualized basis given all of the clinical facts of the case.</i>
p. 1 l. 31	The proposed rule does not require psychological testing but leaves it to the discretion of the provider. The provider may not have had sufficient time with the patient to detect adverse psychological factors.	<i>No action.</i>

**DRAFT Amendments to the Workers' Compensation
Treatment Parameter Rules**

For discussion purposes only - likely to change

August 21, 2008

5221.6030 INCORPORATION BY REFERENCE.

The ICD-9-CM diagnostic codes referenced in parts 5221.6010 to 5221.6600 are contained in the ~~fourth edition of the~~ International Classification of Diseases, Clinical Modification, 9th Revision, 1994, and corresponding annual updates. This document is subject to annual revisions and is incorporated by reference. It is published by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, and may be purchased through the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402. It is available through the Minitex interlibrary loan system.

5221.6040 DEFINITIONS.

[For text of subps 1 to 8, see M.R.]

Subp. 8a. Medical contraindication. "Medical contraindication" means a condition that makes the use of a particular treatment or medication inadvisable because of an increased risk of harm to the patient.

[For text of subps 9 to 10, see M.R.]

[For text of subps 11 to 13, see M.R.]

**5221.6050 GENERAL TREATMENT PARAMETERS; EXCESSIVE TREATMENT;
PRIOR NOTIFICATION.**

Subpart 1. **General.**

[For text of item A, see M.R.]

B. The health care provider must evaluate at each visit whether initial nonsurgical treatment for the low back, cervical, thoracic, and upper extremity, and reflex sympathetic dystrophy conditions specified in parts 5221.6200, 5221.6205, 5221.6210, and 5221.6300, and 5221.6305, is effective according to subitems (1) to (3). No later than any applicable treatment response time in parts 5221.6200 to ~~5221.6300~~ 5221.6305, the health care provider must evaluate whether the passive, active, injection, or medication treatment modality is resulting in progressive improvement as specified in subitems (1) to (3):

[For text of subitems (1) to (3), see M.R.]

[For text of item C, see M.R.]

[For text of subps 2 to 8, see M.R.]

Subp. 9. **Prior notification; health care provider and insurer responsibilities.** Prior notification is the responsibility of the health care provider who wants to provide the treatment in item A. Prior notification need not be given in any case where emergency treatment is required.

[For text of items A and B, see M.R.]

C. The insurer must provide a toll-free facsimile and telephone number for health care providers to provide prior notification. The insurer must respond orally or in writing to the requesting health care provider's prior notification of proposed treatment in item A within seven working days of receipt of the request. Within the seven days, the insurer must either approve the request, deny authorization, request additional information, request that the employee obtain a second opinion, or request an examination by the employer's physician. A denial must include notice to the employee and health care provider of the reason why the information given by the health care provider in item B does not support the treatment proposed, along with notice of the right to review of the denial under subitem (3).

[For text of subitems (1) to (4), see M.R.]

(5) If prior notification of surgery is required under item A, subitem (3), the insurer may require that the employee obtain a second opinion from a physician of the employee's choice under Minnesota Statutes, section 176.135, subdivision 1a. If within seven working days of the prior notification the insurer notifies the employee and health care provider that a second opinion is required, the health care provider may not perform the nonemergency surgery until the employee provides the second opinion to the insurer. Except as otherwise provided in parts 5221.6200, subpart 6, items B and C; 5221.6205, subpart 6, items B and C; 5221.6210, subpart 6, items B and C; 5221.6300, subpart 6, item B; and 5221.6305, subpart 3, item B, if the insurer denies authorization within seven working days of receiving the second opinion, the health care provider may elect to perform the surgery, subject to a determination of compensability by the commissioner or compensation judge under subpart 7.

[For text of subitems (6) and (7), see M.R.]

[For text of subps 10 and 11, see M.R.]

5221.6100 PARAMETERS FOR MEDICAL IMAGING.

[For text of subpart 1, see M.R.]

Subp. 2. Specific imaging procedures for low back pain. Except for the emergency evaluation of significant trauma, a health care provider must document in the medical record an appropriate history and physical examination, along with a review of any existing medical records and laboratory or imaging studies regarding the patient's condition, before ordering any imaging study of the low back.

3.23

[For text of item A, see M.R.]

B. Magnetic resonance imaging (MRI) scanning is indicated any time that one of the following conditions is met:

- (1) when cauda equina syndrome is suspected;
- (2) for evaluation of progressive neurologic deficit;
- (3) when previous spinal surgery to the lumbar spine has been performed and there is a need to differentiate scar due to previous surgery from disc herniation, tumor, or hemorrhage; or
- (4) suspected discitis.

Except as specified in subitems (1) to (4), MRI scanning is not indicated in the first eight weeks after an injury.

Magnetic resonance imaging scanning is indicated after eight weeks if the patient continues with symptoms and physical findings after the course of initial nonsurgical care and if the patient's condition prevents the resumption of the regular activities of daily life including regular vocational activities.

C. Myelography is indicated in the following circumstances:

- (1) may be substituted for otherwise indicated CT scanning or MRI scanning in accordance with items A and B, if those imaging modalities are not locally available;
- (2) in addition to CT scanning or MRI scanning, if there are is progressive neurologic ~~deficits or changes~~ deficit and CT scanning or MRI scanning has been negative; or
- (3) for preoperative evaluation in cases of surgical intervention, but only if CT scanning or MRI scanning have failed to provide a definite preoperative diagnosis.

D. Computed tomography myelography is indicated in the following circumstances:

- (1) the patient's condition is predominantly sciatica, and there has been previous spinal surgery to the lumbar spine, and tumor is suspected;

(2) the patient's condition is predominantly sciatica and there has been previous ~~spinal~~ surgery to the lumbar spine and MRI scanning is equivocal;

(3) when spinal stenosis is suspected and the CT or MRI scanning is equivocal;

(4) in addition to CT scanning or MRI scanning, if there ~~are~~ is progressive neurologic ~~symptoms or changes~~ deficit, and CT scanning or MRI scanning has been negative; or

(5) for preoperative evaluation in cases of surgical intervention, but only if CT scanning or MRI scanning have failed to provide a definite preoperative diagnosis.

E. Intravenous enhanced CT scanning is indicated only if there has been previous ~~spinal~~ surgery to the lumbar spine, and the imaging study is being used to differentiate scar due to previous surgery from disc herniation or tumor, but only if intrathecal contrast for CT myelography is contraindicated and MRI scanning is not available or is also contraindicated.

F. Gadolinium enhanced MRI scanning is indicated when:

(1) there has been previous ~~spinal~~ surgery to the lumbar spine, and the imaging study is being used to differentiate scar due to previous surgery from disc herniation or tumor;

(2) hemorrhage is suspected;

(3) tumor or vascular malformation is suspected;

(4) infection or inflammatory disease is suspected; or

(5) unenhanced MRI scanning was equivocal.

G. Discography is indicated when:

[For text of subitem (1), see M.R.]

(2) there has been previous ~~spinal~~ surgery to the lumbar spine, and pseudoarthrosis, recurrent disc herniation, annular tear, or internal disc disruption is suspected.

[For text of items H to M, see M.R.]

5221.6105 MEDICATIONS.

Subpart 1. Scope. Subparts 2 to 4 do not require a physician to prescribe any class of drugs in the treatment of any patient.

Subp. 2. Nonsteroidal anti-inflammatory drugs (NSAID's). Nonsteroidal anti-inflammatory drugs are drugs with analgesic, antipyretic, and anti-inflammatory effects. The term "nonsteroidal" is used to distinguish these drugs from steroids. NSAID's act as inhibitors of the enzyme cyclooxygenase. For the purposes of this rule, NSAID's include diflunisal but not other salicylates or acetaminophen. NSAID's can be divided into two groups, nonselective NSAID's and COX-2 inhibitors. Examples of nonselective NSAID's include diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, and tolmetin. An example of a COX-2 inhibitor is celecoxib.

A. NSAID's are indicated for the symptomatic relief of acute and chronic musculoskeletal pain. NSAID's must be prescribed at the lowest clinically effective dose, as determined by the prescribing health care provider, but not to exceed the manufacturer's maximum daily dosage.

B. When treating musculoskeletal pain, a generic nonselective NSAID is indicated unless a COX-2 inhibitor is indicated as specified in item C.

(1) When a nonselective NSAID is used, treatment must begin with one of the following: generic ibuprofen, generic naproxen, or generic diclofenac. If there is a medical contraindication documented by the prescribing health care provider to each of the medications in this item, then treatment may begin with any other generic nonselective NSAID.

(2) Other generic nonselective NSAID's are not indicated unless one-week trials of each of ibuprofen, diclogenac, and naproxen have been ineffective in reducing the patient's pain by at least 50 percent as determined by the prescribing health care provider.

(3) Nonselective NSAID's that are not available as generics are not indicated.

C. A COX-2 inhibitor may be indicated instead of a nonselective NSAID for:

(1) patients over 60 years of age;

(2) patients with a history of gastrointestinal bleeding or peptic ulcer disease; or

(3) patients with a history of gastrointestinal side effects with nonselective NSAID use.

However, for any patient meeting any of the criteria of subitems (1) to (3) who is taking aspirin or who is at an increased risk of cardiovascular disease, a COX-2 inhibitor is not indicated and a nonselective NSAID is indicated as allowed in items A and B, together with gastroprotective medication.

D. NSAID's are indicated only for the shortest duration needed as determined by the prescribing health care provider.

(1) NSAID's prescribed within the first four weeks after the date of injury are limited to no more than two weeks of medication per prescription or refill.

(2) NSAID's prescribed more than four weeks after the date of injury may not be for more than one month of medication per prescription or refill.

(3) NSAID's prescribed more than 12 months after the date of injury may not be for more than three months of medication per prescription or refill.

Subp. 3. **Opioid analgesics.** An opioid is any agent that binds to opioid receptors. There are three broad classes of opioids: opium alkaloids, such as morphine and codeine; semisynthetic opioids such as heroin and oxycodone; and fully synthetic opioids such as pethidine and

methadone. Opioid analgesics include codeine, hydrocodone, levorphanol, methadone, morphine, hydromorphone, and oxycodone.

A. Opioid analgesics are indicated for the symptomatic relief of acute and chronic pain that has been inadequately relieved by nonopioid medications. Opioid analgesics must be prescribed at the lowest clinically effective dose, as determined by the prescribing health care provider.

B. When treating pain, a generic oral opioid analgesic is indicated.

(1) When an oral opioid analgesic is used for the symptomatic relief of acute or chronic pain, treatment must begin with one of the following: generic codeine, generic hydrocodone, generic oxycodone, or generic morphine, unless there is a medical contraindication documented by the prescribing health care provider. If there is a medical contraindication documented by the prescribing health care provider to each of the medications in this item, then treatment may begin with any other generic oral opioid analgesic.

(2) Other generic opioid analgesics are not indicated for oral use for the symptomatic relief of acute or chronic pain unless one-week trials of each of codeine, hydrocodone, oxycodone, and morphine have been ineffective in reducing the patient's pain by at least 50 percent as determined by the prescribing health care provider.

(3) Generically available combinations of an oral opioid and a nonopioid analgesic may be prescribed instead of that opioid analgesic as otherwise allowed under subitems (1) and (2).

(4) Oral opioid analgesics that are not available as generics and combinations of an oral opioid analgesic and a nonopioid analgesic that are not available as generics are not indicated.

C. A course of oral opioid analgesics or combination of an oral opioid and a nonopioid analgesic is limited as provided in subitems (1) to (3).

(1) Oral opioid analgesics prescribed within the first four weeks after the date of injury are limited to no more than two weeks of medication per prescription.

(2) Oral opioid analgesics prescribed more than four weeks after the date of injury may not be for more than one month of medication per prescription.

(3) Oral opioid analgesics prescribed more than 12 weeks after the injury may be for more than one month of medication per prescription if there has been a clinical evaluation to confirm the need for and efficacy of the prescription and a clinical evaluation at least every six months thereafter during continued use of opioid analgesics.

D. Meperidine is not indicated in the treatment of acute or chronic pain.

E. Transcutaneous opioid analgesics are only indicated in patients with a documented disorder that prevents adequate oral dosing.

F. Oral transmucosal and buccal preparations are only indicated for the treatment of breakthrough pain and only in patients with a documented disorder that prevents adequate dosing with swallowed medications.

Subp. 4. **Muscle relaxants.** A muscle relaxant is a drug which decreases the tone of a muscle. For the purposes of this part, muscle relaxants include carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine, and tizanide but not other medications that may be used to treat spasticity.

A. Muscle relaxants are indicated for the symptomatic relief of acute and chronic musculoskeletal pain. Muscle relaxants must be prescribed at the lowest clinical effective dose, as determined by the prescribing health care provider, but not to exceed the manufacturer's maximum daily dosage.

B. When treating musculoskeletal pain, a generic muscle relaxant is indicated.

(1) When a muscle relaxant is used, treatment must begin with one of the following: generic carisoprodol, generic chlorzoxazone, generic cyclobenzaprine, generic methocarbamol, or generic tizanide. If there is a medical contraindication documented by the prescribing health care provider to each of the medications in this item, then treatment may begin with any other generic muscle relaxant.

(2) Metaxolone and orphenadrine are not indicated unless one-week trials of each of carisoprodol, chlorzoxazone, cyclobenzaprine, methocarbamol, and tizanide have been ineffective in reducing the patient's pain by at least 50 percent as determined by the prescribing health care provider.

(3) Generically available combinations of a muscle relaxant and an analgesic may be prescribed instead of that muscle relaxant as otherwise allowed under subitems (1) and (2).

(4) Muscle relaxants that are not available as generics, and combinations of a muscle relaxant and an analgesic that are not available as generics, are not indicated.

C. A course of muscle relaxants or combination of a muscle relaxant and an analgesic is limited as provided in subitems (1) to (3).

(1) Muscle relaxants prescribed within the first four weeks after the date of injury are limited to no more than two weeks of medication per prescription or refill.

(2) Muscle relaxants prescribed more than four weeks after the date of injury are limited to no more than one week's worth of medication per prescription or refill.

(3) Treatment with muscle relaxants for more than three consecutive months is not indicated.

D. Benzodiazepines are not indicated as muscle relaxants for the symptomatic relief of acute and chronic musculoskeletal pain.

5221.6200 LOW BACK PAIN.

Subpart 1. **Diagnostic procedures for treatment of low back injury.** A health care provider shall determine the nature of the condition before initiating treatment.

[For text of items A to H, see M.R.]

I. A Comprehensive Functional-functional capacity assessment or evaluation (FCE) is a ~~comprehensive and objective assessment of a patient's ability to perform work tasks~~ an individualized examination and evaluation that objectively measures the patient's current level of function and the ability to perform functional or work-related tasks, and predicts the potential to sustain these tasks over a defined time frame. The components of a ~~functional capacity assessment or evaluation~~ Comprehensive FCE include, but are not limited to, neuromusculoskeletal screening, tests of manual material handling, assessment of functional mobility, and measurement of postural tolerance. ~~A functional capacity assessment or evaluation is an individualized testing process and the component tests and measurements are determined by the patient's condition and the requested information. Functional capacity assessments and evaluations are performed to determine and report a patient's physical capacities in general or to determine work tolerance for a specific job, task, or work activity.~~

(1) ~~Functional capacity assessment or evaluation~~ A Comprehensive FCE is not indicated during the period of initial nonsurgical management.

(2) After the period of initial nonsurgical management ~~functional capacity assessment or evaluation~~ a Comprehensive FCE is indicated in either of the following circumstances:

- (a) permanent activity restrictions and capabilities must be identified; or
- (b) there is a question about the patient's ability to do a specific job.

(3) ~~A functional capacity evaluation~~ Comprehensive FCE is not appropriate indicated to establish baseline performance before treatment, or for subsequent assessments, to evaluate change in performance during or after a course of treatment.

(4) Only one completed ~~functional capacity evaluation~~ Comprehensive FCE is indicated per injury.

(5) Functional tests or physical performance tests done as part of a work conditioning program or work hardening program as provided in part 5221.6600, subpart 2, item D, or in conjunction with active treatment modalities as provided in subpart 4 are not a Comprehensive FCE and are not limited by this rule.

[For text of item J, see M.R.]

[For text of subp 2, see M.R.]

Subp. 3. Passive treatment modalities.

[For text of items A to D, see M.R.]

E. Electrical muscle stimulation includes, but is not limited to, muscle stimulation, low volt therapy, sine wave therapy, stimulation of peripheral nerve, galvanic stimulation, TENS, interferential, and microcurrent techniques.

[For text of subitems (1) and (2), see M.R.]

F. Mechanical traction: is the therapeutic use of mechanically induced tension created by a pulling force to produce a combination of distraction and gliding to relieve pain and increase flexibility. Mechanical traction may be continuous, static, intermittent inversion, gravity, or positional. Mechanical traction includes, but is not limited to, intersegmental motorized mobilization, vertebral axial decompression, autotraction (active), and 90/90.

[For text of subitems (1) and (2), see M.R.]

G. ~~Acupuncture treatment. Endorphin-mediated analgesic therapy includes classic acupuncture and acupressure:~~

[For text of subitems (1) to (3), see M.R.]

H. ~~Manual therapy includes soft tissue and joint mobilization, therapeutic massage, and, but is not limited to, manual traction, myofascial release, joint mobilization and manipulation, manual lymphatic drainage, soft-tissue mobilization and manipulation, trigger point therapy, acupressure, muscle stimulation - manual (nonelectrical), and any form of massage:~~

[For text of subitems (1) to (3), see M.R.]

[For text of items I to K, see M.R.]

[For text of subps 4 to 7, see M.R.]

Subp. 8. **Durable medical equipment.** Durable medical equipment is indicated only in the situations specified in items A to D. The health care provider must provide prior notification as required in items B and C according to part 5221.6050, subpart 9.

[For text of items A to C, see M.R.]

D. The following durable medical equipment is not indicated for home use for any of the low back conditions specified in subpart 1, item A:

[For text of subitems (1) and (2), see M.R.]

[For text of subp 9, see M.R.]

Subp. 10. **Scheduled and nonscheduled medication.** ~~Prescription of controlled substance medications scheduled under Minnesota Statutes, section 152.02, including without limitation, narcotics, is indicated only for the treatment of severe acute pain. These medications are not indicated in the treatment of patients with regional low back pain after the first two weeks.~~

~~Patients with radicular pain may require longer periods of treatment.~~

The health care provider must document the rationale for the use of any scheduled medication. Treatment with ~~non~~scheduled medication may be appropriate during any phase of treatment and ~~intermittently after all other treatment has been discontinued~~ must comply with all of the applicable parameters in part 5221.6105. The prescribing health care provider must determine that ongoing medication is effective treatment for the patient's condition and that the most cost-effective regimen is used.

[For text of subps 11 to 13, see M.R.]

5221.6205 NECK PAIN.

Subpart 1. **Diagnostic procedures for treatment of neck injury.** A health care provider shall determine the nature of the condition before initiating treatment.

[For text of items A to H, see M.R.]

I. A Comprehensive Functional functional capacity assessment or evaluation (FCE) is a comprehensive and objective assessment of a patient's ability to perform work tasks an individualized examination and evaluation that objectively measures the patient's current level of function and the ability to perform functional or work-related tasks, and predicts the potential to sustain these tasks over a defined time frame. The components of a functional capacity assessment ~~or evaluation~~ Comprehensive FCE include, but are not necessarily limited to, neuro-musculoskeletal screening, tests of manual material handling, assessment of functional mobility, and measurement of postural tolerance. ~~A functional capacity assessment or evaluation is an individualized testing process and the component tests and measurements are determined by the patient's condition and the requested information. Functional capacity assessments and evaluations are performed to determine and report a patient's physical capacities in general or to determine work tolerance for a specific job, task, or work activity.~~

(1) ~~Functional capacity assessment or evaluation~~—A Comprehensive FCE is not reimbursable indicated during the period of initial ~~nonoperative care~~ nonsurgical management.

(2) ~~Functional capacity assessment or evaluation~~ After the period of initial nonsurgical management a Comprehensive FCE is reimbursable indicated in either of the following circumstances:

(a) permanent activity restrictions and capabilities must be identified; or

(b) there is a question about the patient's ability to do a specific job.

(3) A Comprehensive FCE is not indicated to establish baseline performance before treatment, or to evaluate change in performance during a course of treatment.

(4) Only one completed Comprehensive FCE is indicated per injury.

(5) Functional tests or physical performance tests done as part of a work conditioning program or work hardening program as provided in part 5221.6600, subpart 2, item D, or in conjunction with active treatment modalities as provided in subpart 4 are not a Comprehensive FCE and are not limited by this rule.

[For text of item J, see M.R.]

[For text of subp 2, see M.R.]

Subp. 3. Passive treatment modalities.

[For text of items A to D, see M.R.]

E. Electrical muscle stimulation includes, but is not limited to, muscle stimulation, low volt therapy, sine wave therapy, stimulation of peripheral nerve, galvanic stimulation, TENS, interferential, and microcurrent techniques.

[For text of subitems (1) and (2), see M.R.]

F. Mechanical traction: is the therapeutic use of mechanically induced tension created by a pulling force to produce a combination of distraction and gliding to relieve pain and increase flexibility. Mechanical traction may be continuous, static, intermittent, inversion, gravity, or positional. Mechanical traction includes, but is not limited to, intersegmental motorized mobilization, vertebral axial decompression, autotraction (active), and 90/90.

[For text of subitems (1) and (2), see M.R.]

G. Acupuncture treatments. ~~Endorphin-mediated analgesic therapy includes classic acupuncture and acupressure:~~

[For text of subitems (1) to (3), see M.R.]

H. Manual therapy includes ~~soft tissue and joint mobilization, therapeutic massage, and,~~ but is not limited to, manual traction, myofascial release, joint mobilization and manipulation, manual lymphatic drainage, soft-tissue mobilization and manipulation, trigger point therapy, acupressure, muscle stimulation - manual (nonelectrical), and any form of massage:

[For text of subitems (1) to (3), see M.R.]

[For text of items I to K, see M.R.]

[For text of subps 4 to 7, see M.R.]

Subp. 8. Durable medical equipment. Durable medical equipment is indicated only as specified in items A to D. The health care provider must provide prior notification as required in items B and C according to part 5221.6050, subpart 9.

[For text of items A to C, see M.R.]

D. The following durable medical equipment is not indicated for home use for any of the neck pain conditions specified in subpart 1, item A:

[For text of subitems (1) and (2), see M.R.]

[For text of subp 9, see M.R.]

Subp. 10. **Scheduled and nonscheduled medication.** ~~Prescription of controlled substance medications scheduled under Minnesota Statutes, section 152.02, including without limitation, narcotics, is indicated only for the treatment of severe acute pain. These medications are not indicated in the treatment of patients with regional neck pain after the first two weeks.~~

~~Patients with radicular pain may require longer periods of treatment.~~

The health care provider must document the rationale for the use of any ~~scheduled~~ medication. Treatment with ~~nonnarcotic~~ medication may be appropriate during any phase of treatment and ~~intermittently after all other treatment has been discontinued~~ must comply with all of the applicable parameters in part 5221.6105. The prescribing health care provider must determine that ongoing medication is effective treatment for the patient's condition and that the most cost-effective regimen is used.

[For text of subps 11 to 14, see M.R.]

5221.6210 THORACIC BACK PAIN.

Subpart 1. **Diagnostic procedures for treatment of thoracic back injury.** A health care provider shall determine the nature of the condition before initiating treatment.

[For text of items A to H, see M.R.]

I. A Comprehensive Functional-functional capacity assessment or evaluation (FCE) is a comprehensive and objective assessment of a patient's ability to perform work tasks an individualized examination and evaluation that objectively measures the patient's current level of function and the ability to perform functional or work-related tasks, and predicts the potential to sustain these tasks over a defined time frame. The components of a ~~functional capacity assessment or evaluation~~ Comprehensive FCE include, but are not limited to, neuromusculoskeletal screening,

tests of manual material handling, assessment of functional mobility, and measurement of postural tolerance. ~~A functional capacity assessment or evaluation is an individualized testing process and the component tests and measurements are determined by the patient's condition and the requested information. Functional capacity assessments and evaluations are performed to determine and report a patient's physical capacities in general or to determine work tolerance for a specific job, task, or work activity.~~

(1) ~~Functional capacity assessment or evaluation~~ A Comprehensive FCE is not reimbursable indicated during the period of initial nonoperative care- nonsurgical management.

(2) ~~Functional capacity assessment or evaluation~~ After the period of initial nonsurgical management a Comprehensive FCE is reimbursable indicated in either of the following circumstances:

(a) permanent activity restrictions and capabilities must be identified; or

(b) there is a question about the patient's ability to do a specific job.

(3) A Comprehensive FCE is not indicated to establish baseline performance before treatment, or to evaluate change in performance during a course of treatment.

(4) Only one completed Comprehensive FCE is indicated per injury.

(5) Functional tests or physical performance tests done as part of a work conditioning program or work hardening program as provided in part 5221.6600, subpart 2, item D, or in conjunction with active treatment modalities as provided in subpart 4 are not a Comprehensive FCE and are not limited by this rule.

[For text of item J, see M.R.]

[For text of subp 2, see M.R.]

Subp. 3. **Passive treatment modalities.**

[For text of items A to D, see M.R.]

E. Electrical muscle stimulation includes, but is not limited to, muscle stimulation, low volt therapy, sine wave therapy, stimulation of peripheral nerve, galvanic stimulation, TENS, interferential, and microcurrent techniques.

[For text of sub items (1) and (2), see M.R.]

F. Mechanical traction: is the therapeutic use of mechanically induced tension created by a pulling force to produce a combination of distraction and gliding to relieve pain and increase flexibility. Mechanical traction may be continuous, static, intermittent, inversion, gravity, or positional. Mechanical traction includes, but is not limited to, intersegmental motorized mobilization, vertebral axial decompression, autotraction (active), and 90/90.

[For text of subitems (1) and (2), see M.R.]

G. Acupuncture treatment. ~~Endorphin-mediated analgesic therapy includes classic acupuncture and acupressure:~~

[For text of subitems (1) to (3), see M.R.]

H. Manual therapy includes ~~soft tissue and joint mobilization, therapeutic massage, and,~~ but is not limited to, manual traction, myofascial release, joint mobilization and manipulation, manual lymphatic drainage, soft-tissue mobilization and manipulation, trigger point therapy, acupressure, muscle stimulation - manual (nonelectrical), and any form of massage:

[For text of subitems (1) to (3), see M.R.]

[For text of items I to K, see M.R.]

[For text of subps 4 to 7, see M.R.]

Subp. 8. **Durable medical equipment.** Durable medical equipment is indicated only in certain specific situations, as specified in items A to D. The health care provider must provide the insurer with prior notification as required by items B and C, according to part 5221.6050, subpart 9.

[For text of items A to C, see M.R.]

D. The following durable medical equipment is not indicated for home use for any of the thoracic back pain conditions specified in subpart 1, item A:

[For text of subitems (1) and (2), see M.R.]

[For text of subp 9, see M.R.]

Subp. 10. **Scheduled and nonscheduled medication.** ~~Prescription of controlled substance medications scheduled under Minnesota Statutes, section 152.02, including without limitation, narcotics, is indicated only for the treatment of severe acute pain. These medications are not indicated in the treatment of patients with regional thoracic back pain after the first two weeks.~~

~~Patients with radicular pain may require longer periods of treatment.~~

The health care provider must document the rationale for the use of any ~~scheduled~~ medication. Treatment with ~~nonnarcotic~~ medication may be appropriate during any phase of treatment and ~~intermittently after all other treatment has been discontinued~~ must comply with all of the applicable parameters in part 5221.6105. The prescribing health care provider must determine that ongoing medication is effective treatment for the patient's condition and that the most cost-effective regimen is used.

[For text of subps 11 to 13, see M.R.]

5221.6300 UPPER EXTREMITY DISORDERS.

Subpart 1. **Diagnostic procedures for treatment of upper extremity disorders (UED).** A health care provider shall determine the nature of an upper extremity disorder before initiating treatment.

[For text of items A to D, see M.R.]

E. The following diagnostic procedures or tests are not indicated for the diagnosis of upper extremity disorders any of the clinical categories in item A:

[For text of subitems (1) to (3), see M.R.]

[For text of items F to I, see M.R.]

J. A Comprehensive Functional-functional capacity assessment or evaluation (FCE) is a comprehensive and objective assessment of a patient's ability to perform work tasks an individualized examination and evaluation that objectively measures the patient's current level of function and the ability to perform functional or work-related tasks, and predicts the potential to sustain these tasks over a defined time frame. The components of a functional capacity assessment or evaluation Comprehensive FCE include, but are not limited to, neuromusculoskeletal screening, tests of manual material handling, assessment of functional mobility, and measurement of postural tolerance. A functional capacity assessment or evaluation is an individualized testing process and the component tests and measurements are determined by the patient's condition and the required information. Functional capacity assessments and evaluations are performed to determine and report a patient's physical capacities in general or to determine work tolerance for a specific job, task, or work activity.

(1) Functional capacity assessment or evaluation A Comprehensive FCE is not indicated during the first 12 weeks of period of initial nonsurgical treatment management.

(2) Functional capacity assessment or evaluation After the period of initial nonsurgical management Comprehensive FCE is indicated after the first 12 weeks of care in either of the following circumstances:

(a) permanent activity restrictions and capabilities must be identified; or

(b) there is a question about the patient's ability to ~~return to~~ do a specific job.

(3) ~~A functional capacity evaluation~~ Comprehensive FCE is not ~~appropriate~~ indicated to establish baseline performance before treatment, or ~~for subsequent assessments,~~ to evaluate change in performance during or after a course of treatment.

(4) Only one completed ~~functional capacity evaluation~~ Comprehensive FCE is indicated per injury.

~~(5) Functional tests or physical performance tests done as part of a work conditioning program or work hardening program as provided in part 5221.6600, subpart 2, item D, or in conjunction with active treatment modalities as provided in subpart 4 are not a~~ Comprehensive FCE and are not limited by this rule.

[For text of item K, see M.R.]

[For text of subp 2, see M.R.]

Subp. 3. Passive treatment modalities.

[For text of items A to D, see M.R.]

E. Electrical muscle stimulation includes, but is not limited to, muscle stimulation, low volt therapy, sine wave therapy, stimulation of peripheral nerve, galvanic stimulation, TENS, interferential, and microcurrent techniques.

[For text of subitems (1) and (2), see M.R.]

F. ~~Acupuncture treatments. Endorphin-mediated analgesic therapy includes classic acupuncture and acupressure:~~

[For text of subitems (1) to (3), see M.R.]

[For text of item G, see M.R.]

H. Manual therapy includes ~~soft tissue and joint mobilization and therapeutic massage, but~~ is not limited to, manual traction, myofascial release, joint mobilization and manipulation, manual lymphatic drainage, soft-tissue mobilization and manipulation, trigger point therapy, acupressure, muscle stimulation - manual (nonelectrical), and any form of massage:

[For text of subitems (1) to (3), see M.R.]

[For text of items I and J, see M.R.]

[For text of subps 4 to 7, see M.R.]

Subp. 8. **Durable medical equipment.** Durable medical equipment is indicated only in the situations specified in items A to D. The health care provider must provide the insurer with prior notification as required in items B and C and part 5221.6050, subpart 9.

[For text of items A to C, see M.R.]

D. The following durable medical equipment is not indicated for home use for the upper extremity disorders specified in ~~subparts 11 to 16~~ subpart 1, item A:

[For text of subitems (1) and (2), see M.R.]

[For text of subp 9, see M.R.]

Subp. 10. **Scheduled and nonscheduled medication.** ~~Prescription of controlled substance medications scheduled under Minnesota Statutes, section 152.02, including without limitation, narcotics, is indicated only for the treatment of severe acute pain. Therefore, these medications are not routinely indicated in the treatment of patients with upper extremity disorders. The health care provider must document the rationale for the use of any scheduled medication. Treatment with nonscheduled medication may be appropriate during any phase of treatment and intermittently after all other treatment has been discontinued~~ must comply with all of the applicable parameters in part

5221.6105. The prescribing health care provider must determine that ongoing medication is effective treatment for the patient's condition and that the most cost-effective regimen is used.

[For text of subps 11 to 16, see M.R.]

5221.6305 COMPLEX REGIONAL PAIN SYNDROME (CRPS) / REFLEX SYMPATHETIC DYSTROPHY OF THE UPPER AND LOWER EXTREMITIES.

Subpart 1. **Scope.**

A. This clinical category encompasses:

(1) any condition diagnosed as reflex sympathetic dystrophy, causalgia, complex regional pain syndrome, Sudek's atrophy, algoneurodystrophy, or shoulder-hand syndrome, including, but not limited to, ICD-9-CM codes 337.9, 354.4, and 733.7; or

(2) any condition of the upper or lower extremity characterized by concurrent presence in the involved extremity of five of the following conditions: edema; local skin color change of red or purple; osteoporosis in underlying bony structures demonstrated by radiograph; local dyshidrosis; local abnormality of skin temperature regulation; reduced passive range of motion in contiguous joints; local alteration of skin texture of smooth or shiny; or typical findings of reflex sympathetic dystrophy on bone scan. This clinical category includes, but is not limited to, the diagnoses of reflex sympathetic dystrophy, causalgia, Sudek's atrophy, algoneurodystrophy, and shoulder hand syndrome, and including, but not limited to, ICD-9-CM codes 337.9, 254.4, and 733.7; or

(3) any condition of the upper or lower extremity that develops after trauma or nerve injury and is characterized by continuing pain, allodynia, or hyperalgesia that is nonanatomic in distribution and disproportionate to the original injury and to stimulation, and the patient has or has

had edema, vasomotor abnormality, or sudomotor abnormality on examination, and there is no other explanation for the degree of pain and dysfunction.

[For text of items B and C, see M.R.]

Subp. 2. **Initial nonsurgical management.** Initial nonsurgical management is appropriate for all patients with reflex sympathetic dystrophy and must be the first phase of treatment. Any course or program of initial nonsurgical management is limited to the modalities specified in items A to D.

A. Therapeutic injection modalities. The only injections allowed for reflex sympathetic dystrophy are sympathetic block, intravenous infusion of steroids or sympatholytics, or epidural block.

(1) Unless medically contraindicated, sympathetic blocks or the intravenous infusion of steroids or sympatholytics must be used if reflex sympathetic dystrophy has continued for four weeks and the employee remains disabled as a result of the reflex sympathetic dystrophy.

(a) Time for treatment response: within 30 minutes.

(b) Maximum treatment frequency: can repeat an injection ~~at a site~~ to a limb if there was a positive response to the first injection. If subsequent injections demonstrate diminishing control of symptoms or fail to facilitate objective functional gains, then injections must be discontinued. No more than three injections to different sites limbs are reimbursable per patient visit.

[For text of unit (c), see M.R.]

[For text of subitem (2), see M.R.]

[For text of items B and C, see M.R.]

D. ~~Oral medications may be indicated in accordance with accepted medical practice~~ The health care provider must document the rationale for the use of any medication. Treatment with

medication may be appropriate during any phase of treatment and must comply with all of the applicable parameters in part 5221.6105. The prescribing health care provider must determine that ongoing medication is effective treatment for the patient's condition and that the most cost-effective regimen is used.

[For text of subps 3 and 4, see M.R.]

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 **5221.6200 Low Back Pain**
2

3 Subp. 6. Surgery, including decompression procedures and arthrodesis. Surgery may only be
4 performed if it also meets the specific parameters specified in subparts 11 to 13 and part
5 5221.6500. The health care provider must provide prior notification of nonemergency inpatient
6 surgery according to part 5221.6050, subpart 9.
7

8 A. In order to optimize the beneficial effect of surgery, postoperative therapy with active and
9 passive treatment modalities may be provided, even if these modalities had been used in the
10 preoperative treatment of the condition. In the postoperative period the maximum treatment
11 duration with passive treatment modalities in a clinical setting from the initiation of the first
12 passive modality used, except bedrest or bracing, is as follows:
13

14 (1) eight weeks following lumbar decompression or implantation of a dorsal column
15 stimulator or morphine pump spinal cord stimulator or intrathecal drug delivery system;
16

17 or

18 (2) 12 weeks following arthrodesis.

19 B. Repeat surgery must also meet the parameters of subparts 11 to 13 and part 5221.6500, and is
20 not indicated unless the need for the repeat surgery is confirmed by a second opinion obtained
21 before surgery, if a second opinion is requested by the insurer.
22

23 C. ~~The following surgical therapies~~ Spinal cord stimulators have very limited application as
24 provided in subitems (1) and (2). And require a second opinion that confirms that the treatment is
25 indicated and within the parameters listed, and a personality or psychosocial evaluation that
26 indicates that the patient is likely to benefit from the treatment.

27 (1) A trial screening period of these devices is indicated only if the treating health care
28 provider determines and a second opinion confirms that:

29 (a) the patient has intractable pain;

30 (b) the patient is not a candidate for another surgical therapy; and

31 (c) the patient has no psychological contraindications to this treatment. The
32 treating health care provider shall refer the patient for a consultation if the
33 provider feels unable to assess the patient for psychological contraindications.
34

35 (2) Long term use of a spinal cord stimulator is indicated if the treating health care
36 provider documents that there has been at least a 50% improvement in pain during a trial
37 screening period of at least three days.
38

39 ~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is~~
40 ~~not a candidate for any other surgical therapy, and has had a favorable response to a trial~~
41 ~~screening period.~~

42 ~~(2) Morphine pump is indicated for a patient who has somatic pain, and is not a~~
43 ~~candidate for any other surgical therapy, and has had a favorable response to a trial~~
44 ~~screening period.~~

45 D. Intrathecal drug delivery systems. ... [draft rule under development]

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 Subp. 11. B
2

3 (6) The only surgical procedures indicated for patients with regional low back pain only
4 are decompression of a lumbar nerve root or lumbar arthrodesis, with or without
5 instrumentation, which must meet the parameters of subpart 6 and part 5221.6500,
6 subpart 2, items A and C. For patients with failed back surgery, ~~dorsal column~~
7 ~~stimulators or morphine pumps~~ a spinal cord stimulator or an intrathecal drug delivery
8 system may be indicated; their use must meet the parameters of subpart 6, item C.

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 **5221.6200 Neck Pain**
2

3 Subp. 6. Surgery, including decompression procedures and arthrodesis. Surgery may only be
4 performed if it meets the specific parameters of subparts 11 to 14 and part 5221.6500. The health
5 care provider must provide prior notification for nonemergency inpatient surgery according to
6 part 5221.6050, subpart 9.
7

8 A. In order to optimize the beneficial effect of surgery, postoperative therapy with active and
9 passive treatment modalities may be provided, even if these modalities had been used in the
10 preoperative treatment of the condition. In the postoperative period the maximum treatment
11 duration with passive treatment modalities in a clinical setting from the initiation of the first
12 passive modality used, except bedrest or bracing, is as follows:
13

- 14 (1) ~~eight weeks following decompression or implantation of a dorsal column stimulator or~~
15 ~~morphine pump spinal cord stimulator or intrathecal drug delivery system;~~ or
16 (2) 12 weeks following arthrodesis.
17

18 B. Repeat surgery must also meet the parameters of subparts 11 to 14 and part 5221.6500 and is
19 not indicated unless the need for the repeat surgery is confirmed by a second opinion obtained
20 before surgery, if requested by the insurer.
21

22 C. ~~The following surgical therapies~~ Spinal cord stimulators have very limited application as
23 provided in subitems (1) and (2). And require a second opinion that confirms that the treatment is
24 indicated and within the parameters listed, and a personality or psychosocial evaluation that
25 indicates that the patient is likely to benefit from the treatment.

26 (1) A trial screening period of these devices is indicated only if the treating health care
27 provider determines and a second opinion confirms that:

- 28 (a) the patient has intractable pain;
29 (b) the patient is not a candidate for another surgical therapy; and
30 (c) the patient has no psychological contraindications to this treatment. The
31 treating health care provider shall refer the patient for a consultation if the
32 provider feels unable to assess the patient for psychological contraindications.
33

34 (2) Long term use of a spinal cord stimulator is indicated if the treating health care
35 provider documents that there has been at least a 50% improvement in pain during a trial
36 screening period of at least three days.
37

38 ~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is~~
39 ~~not a candidate for any other surgical therapy, and has had a favorable response to a trial~~
40 ~~screening period.~~

41 ~~(2) Morphine pump is indicated for a patient who has somatic pain, and is not a~~
42 ~~candidate for any other surgical therapy, and has had a favorable response to a trial~~
43 ~~screening period.~~

44 D. Intrathecal drug delivery systems. ... [draft rule under development]
45

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 Subpart 11 B
2

3 (6) The only surgical procedure indicated for patients with regional neck pain only is cervical
4 arthrodesis, with or without instrumentation, which must meet the parameters of subpart 6. For
5 patients with failed surgery, ~~dorsal column stimulators or morphine pumps~~ a spinal cord
6 stimulator or an intrathecal drug delivery system may be indicated consistent with the parameters
7 of subpart 6, item C.
8

9 Subpart 12
10

11 B. Surgical evaluation or chronic management is indicated if the patient continues with
12 symptoms and physical findings after the course of initial nonsurgical care, and if the patient's
13 condition prevents the resumption of the regular activities of daily life including regular
14 vocational activities. It must be provided within the parameters of subpart 11, item B, with the
15 following modifications: the only surgical procedures indicated for patients with radicular pain
16 are decompression of a cervical nerve root which must meet the parameters of subpart 6 and part
17 5221.6500, subpart 2, item B, and cervical arthrodesis, with or without instrumentation. For
18 patients with failed surgery, ~~dorsal column stimulators or morphine pumps~~ a spinal cord
19 stimulator or an intrathecal drug delivery system may be indicated consistent with subpart 6, item
20 C.
21

22 Subpart 13 A
23

24 (2) the only surgical procedures indicated for patients with radicular pain are decompression of a
25 cervical nerve root which must meet the parameters of subpart 6 and part 5221.6500, subpart 2,
26 item B, or cervical arthrodesis, with or without instrumentation. For patients with failed back
27 surgery, ~~dorsal column stimulators or morphine pumps~~ a spinal cord stimulator or an intrathecal
28 drug delivery system may be indicated consistent with the parameters of subpart 6, item C.
29

30 Subpart 14 A
31

32 (2) the only surgical procedures indicated for patients with myelopathy are anterior or posterior
33 decompression of the spinal cord, or cervical arthrodesis with or without instrumentation. For
34 patients with failed back surgery, ~~dorsal column stimulators or morphine pumps~~ a spinal cord
35 stimulator or an intrathecal drug delivery system may be indicated consistent with the parameters
36 of subpart 6, item C.
37

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 **5221.6210 Thoracic Back Pain**
2

3 Subp. 6. Surgery, including decompression procedures. Surgery may only be performed if it
4 meets the specific parameters of subparts 11 to 13 and part 5221.6500. The health care provider
5 must provide prior notification of nonemergency inpatient surgery according to part 5221.6050,
6 subpart 9.
7

8 A. In order to optimize the beneficial effect of surgery, postoperative therapy with active and
9 passive treatment modalities may be provided, even if these modalities had been used in the
10 preoperative treatment of the condition. In the postoperative period the maximum treatment
11 duration with passive treatment modalities in a clinical setting from the initiation of the first
12 passive modality used, except bedrest or bracing, is as follows:
13

- 14 (1) eight weeks following decompression or implantation of a ~~dorsal column stimulator or~~
15 ~~morphine pump spinal cord stimulator or intrathecal drug delivery system;~~ or
16 (2) 12 weeks following arthrodesis.
17

18 B. Repeat surgery must also meet the parameters of subparts 11 to 13 and part 5221.6500 and is
19 not indicated unless the need for the repeat surgery is confirmed by a second opinion obtained
20 before surgery, if a second opinion is requested by the insurer.
21

22 C. ~~The following surgical therapies~~ Spinal cord stimulators have very limited application as
23 provided in subitems (1) and (2). And require a second opinion that confirms that the treatment is
24 indicated and within the parameters listed, and a personality or psychosocial evaluation that
25 indicates that the patient is likely to benefit from the treatment.

26 (1) A trial screening period of these devices is indicated only if the treating health care
27 provider determines and a second opinion confirms that:

- 28 (a) the patient has intractable pain;
29 (b) the patient is not a candidate for another surgical therapy; and
30 (c) the patient has no psychological contraindications to this treatment. The
31 treating health care provider shall refer the patient for a consultation if the
32 provider feels unable to assess the patient for psychological contraindications.
33

34 (2) Long term use of a spinal cord stimulator is indicated if the treating health care
35 provider documents that there has been at least a 50% improvement in pain during a trial
36 screening period of at least three days.
37

38 ~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is~~
39 ~~not a candidate for any other surgical therapy, and has had a favorable response to a trial~~
40 ~~screening period.~~

41 ~~(2) Morphine pump is indicated for a patient who has somatic pain, and is not a~~
42 ~~candidate for any other surgical therapy, and has had a favorable response to a trial~~
43 ~~screening period.~~

44 D. Intrathecal drug delivery systems. ... [draft rule under development]
45

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 Subpart 11 B

2

3 (6) The only surgical procedure indicated for patients with regional thoracic back pain only is
4 thoracic arthrodesis with or without instrumentation, which must meet the parameters of subpart
5 6, and part 5221.6500, subpart 2, item C. For patients with failed surgery, ~~dorsal column~~
6 ~~stimulators or morphine pumps~~ a spinal cord stimulator or an intrathecal drug delivery system
7 may be indicated consistent with subpart 6, item C.

8

9 Subpart 12

10

11 B. Surgical evaluation or chronic management is indicated if the patient continues with
12 symptoms and physical findings after the course of initial nonsurgical care, and if the patient's
13 condition prevents the resumption of the regular activities of daily life including regular
14 vocational activities. It shall be provided within the parameters of subpart 11, item B, with the
15 following modifications: the only surgical procedures indicated for patients with radicular pain
16 are decompression or arthrodesis. For patients with failed surgery, ~~dorsal column stimulators or~~
17 ~~morphine pumps~~ a spinal cord stimulator or an intrathecal drug delivery system may be indicated
18 consistent with subpart 6, item C.

19

20 Subpart 13 A

21

22 (2) the only surgical procedures indicated for patients with myelopathy are decompression and
23 arthrodesis. For patients with failed surgery, ~~dorsal column stimulators or morphine pumps~~ a
24 spinal cord stimulator or an intrathecal drug delivery system may be indicated consistent with
25 subpart 6, item C.

Spinal Cord Stimulators and Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 02/05/08

1 5221.6305 Reflex Sympathetic Dystrophy of the Upper and Lower Extremities.

2
3 Subp. 3. Surgery.

4
5 A. Surgical sympathectomy may only be performed in patients who had a sustained but
6 incomplete improvement with sympathetic blocks by injection.

7
8 B.) Dorsal column stimulator or morphine pump may be indicated for a patient with neuropathic
9 pain unresponsive to all other treatment modalities who is not a candidate for any other therapy
10 and has had a favorable response to a trial screening period. Use of these devices is indicated
11 only if a second opinion confirms that this treatment is indicated, and a personality or
12 psychosocial evaluation indicates that the patient is likely to benefit from this treatment.
13 Spinal cord stimulators have very limited application as provided in subitems (1) and (2).

14 (1) A trial screening period of these devices is indicated only if the treating health care
15 provider determines and a second opinion confirms that:

16 (a) the patient has intractable pain;

17 (b) the patient is not a candidate for another surgical therapy; and

18 (c) the patient has no psychological contraindications to this treatment. The
19 treating health care provider shall refer the patient for a consultation if the
20 provider feels unable to assess the patient for psychological contraindications.

21
22 (2) Long term use of a spinal cord stimulator is indicated if the treating health care
23 provider documents that there has been at least a 50% improvement in pain during a trial
24 screening period of at least three days.

25
26 C. Intrathecal drug delivery systems. ... [draft rule under development]
27

Comments Received and Recommendations Re: Proposed Rules for Spinal Cord Stimulators

	Comment	Recommendation
<p>p. 1 l. 31</p>	<p>What are the psychological contraindications?</p>	<p>No change. While guidelines state that “evident unresolved major psychiatric comorbidity” is a contraindication, specific disorders are not identified in the guidelines. This is a clinical judgment made on an individualized basis given all of the clinical facts of the case.</p>
<p>p. 1 l. 31</p>	<p>The proposed rule does not require psychological testing but leaves it to the discretion of the provider. The provider may not have had sufficient time with the patient to detect adverse psychological factors.</p>	

DRAFT REPORT

Spinal Cord Stimulators

September 2, 2008

The Department has prepared this report spinal cord stimulators in accordance with the guidelines and formats used in the MSRB Charge to its Medications Task Force (October 14, 2004 MSRB meeting). The overall clinical question considered in this review was:

1. What is the proper use of spinal cord stimulators in the treatment of chronic spinal pain and complex regional pain syndrome (reflex sympathetic dystrophy)?

This overall question was addressed by identifying and synthesizing the best available medical data on the following specific issues:

Are spinal cord stimulators *effective* in the treatment of chronic spinal pain and complex regional pain syndrome (reflex sympathetic dystrophy)?

Are spinal cord stimulators *safe*?

What is the appropriate trial period for determining if a patient will have a favorable response to treatment with a spinal cord stimulator?

What are the appropriate criteria for judging whether a patient had a favorable response during a trial period?

Department Work Plan

The Department used the same “evidence-based medicine” approach to spinal cord stimulators as had been employed by the MSRB’s Medications Task Force in preparing its report on non-steroidal anti-inflammatory drugs (NSAIDs)¹. Evidence-Based Medicine (EBM) “is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.”² EBM replaces clinical intuition, observations from personal clinical experience, and hypothetical arguments based on pathophysiological principles, as the principle grounds for clinical decision-making. Instead evidence from systematic surveys and critical appraisals of peer-reviewed, methodologically-sound clinical research is gathered, reviewed and synthesized using standardized, objective protocols based on agreed rules of evidence.

Key components of the evidence-based medicine approach used by the Department are:

- a) the systematic search for, and retrieval of, all the relevant medical literature regarding the use of spinal cord stimulators that addresses one or more of the specific issues listed above;
- b) sorting the retrieved literature by level of evidence;
- c) critical appraisal of that literature to systematically examine its validity, results and relevance; and,
- d) synthesis of the findings, with a grade of recommendation.

1 Final Report. MSRB Task Force On Medications. Nonsteroidal Anti-Inflammatory Drugs, July 21, 2005

2 Rosenberg W, Donald A. “Evidence-based medicine: an approach to clinical problem solving” BMJ 1995; 310(6987): 1122–1126

Strauss SE, Richardson WS, Glasziou P, Haynes RB Evidence-based Medicine: How to Practice and Teach EBM Edinburgh; Churchill Livingstone, 2005

The search and retrieval of the medical literature was done using computerized search engines and on-line bibliographical databases of the medical literature. In order to maximize the efficient use of time and resources, the same strategies as used by the MSRB's Medications Task Force in its analysis on NSAIDs were adopted to target the searches to the best and most recent evidence by using a step-wise search process.

First, the Department searched the medical literature by "level of evidence." The levels of evidence (Table 1) are a hierarchy representing the strength of the conclusion that can be drawn from a study of that type. Level I evidence is the most compelling, while Level VI evidence is the weakest. The Department restricted the initial search of the medical literature to Level I evidence – systematic reviews and meta-analyses. A systematic review is itself a review of the medical literature conducted using methods (including systematic search and retrieval of all the relevant primary source evidence and critical appraisal of the evidence found using standardized techniques) designed to minimize the likelihood of bias in the results. A meta-analysis is a systematic review in which quantitative methods are used to summarize the results of the review³. Not only are systematic reviews and meta-analyses the strongest evidence available but they have the additional property of representing the other levels of evidence.

Table 1: Levels of Evidence⁴

I	systematic reviews/meta-analyses of multiple randomized, controlled trials
II	randomized, controlled trials
IIIA	controlled studies without randomization
IIIB	other types of quasi-experimental study
IV	non-experimental descriptive studies
V	case series
VI	expert committee reports or opinions/clinical experience of respected authorities, or both

Using Level I evidence means that the Department could review efforts by other researchers who had already searched the medical literature for Level II and higher evidence, retrieved and reviewed these studies to determine their relevance and methodological quality, abstracted and evaluated their findings, and synthesized the results. This allowed the Department to leverage its resources to review a much larger body of evidence.

Second, the Department tried to focus the search on the most recent studies, so as to best represent the most current information.

The Department also searched for any already published, evidence-based guidelines for the use of spinal cord stimulators.

³ Guyatt G, Rennie D *Users' Guides to the Medical Literature. Essentials of Evidence-Based Clinical Practice* AMA Press, 2002
FOCUS "Critical Appraisal Tool" at <http://www.focusproject.org.uk/>

⁴ Adapted from Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M "Levels of Evidence and Grades of Recommendation" Oxford Centre for Evidence-based Medicine, 1998 http://www.cebm.net/levels_of_evidence.asp

Prior to beginning the literature search, the Department adopted a set of guidelines for determining when and how the searches would be extended that were similar to those used by the MSRB's Medications Task Force in its analysis on NSAIDs. If at least 10 valid and unrelated references to systematic reviews were not found, the search would be extended to look for all articles in category II (randomized controlled trials) and for all articles in category I (systematic reviews) in the entire database.

The search for relevant medical literature was in fact extended to all levels of evidence. And the search was extended back in time to encompass all of the available literature in the on-line databases.

The Department conducted the literature searches in two electronic bibliographic databases:

1. Medline through the PubMed portal at <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi> ; and,
2. The Cochrane Library (The Cochrane Database of Systematic Reviews, Database of Abstracts of reviews of Effects, and The Cochrane Central Register of Controlled Trials) through the Lumina portal of the University of Minnesota Libraries at http://tc.liblink.umn.edu/sfx_local/a-z/default.

PubMed is a service of the National Library of Medicine (NLM) available via the National Center of Biotechnology's Entrez retrieval system. PubMed is a public access search engine for MEDLINE, NLM's premier bibliographic database for medical literature. MEDLINE contains bibliographic citations and author abstracts from more than 4,800 biomedical journals published in the United States and 70 other countries. The database contains over 12 million citations dating back to mid-1960.

The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases created by the Cochrane Collaboration, an international non-profit independent organization of health care providers and health care researchers. The Cochrane Library is a collection of evidence-based medicine databases, which is up-dated quarterly from the best available information about healthcare interventions found in both published and unpublished medical studies from around the world. The Cochrane Database of Systematic Reviews (CDSR) is the collection of systematic reviews done by Cochrane Collaboration work groups. The Database of Abstracts of Reviews of Effects (DARE) contains summaries of systematic reviews done by others, which have met strict quality criteria established by the Cochrane Collaboration. Included reviews have to be about the effects of interventions. The Cochrane Central Register of Controlled Trials (CENTRAL) includes details of clinical trials found in bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources.

The Department used the same inclusion criteria used by the MSRB's Medications Task Force in its analysis on NSAIDs to determine which of the studies found in the automated searches would be retrieved for further analysis. First, the title of the article was reviewed to confirm that the article was about the therapeutic use of spinal cord stimulators in humans. The abstracts and bibliographical data were then retrieved for articles meeting the first screening and reviewed to determine if:

- the article addressed one of the specific issues of relevance about spinal cord stimulators;
- the article represented a study of the appropriate level of evidence;
- it was a study published during the search time frame;
- the article was published in English; and
- the article was available on-line through the University of Minnesota Bio-Medical Library.

Articles selected for inclusion after a review of the article abstract were retrieved in electronic format from the University of Minnesota Bio-Medical Library through the Lumina portal. An electronic database was created listing the authors, the title of the article, and the journal reference. Each article's abstract and full text was then hyperlinked to its citation in the database. Retrieved articles were evaluated for their level of evidence and assigned a "relevance" category. Systematic reviews (and/or meta-analyses) and randomized controlled trials were considered to be of "high" relevance. Other types of controlled trials and economic evaluations were considered to be of "medium" relevance. Unsystematic reviews, editorials, case series, case studies and all other types of articles were considered to be of "low" relevance.

An additional computerized search for guidelines, using the key words "pain" and "spinal cord stimulation" was conducted at the websites of organizations known to be active in guideline development, appraisal, or cataloging:

Country	Name of organization	Website
Netherlands	Dutch Institute for Healthcare Improvement	http://www.cbo.nl
New Zealand	New Zealand Guidelines Group	http://www.nzgg.org.nz
	Accident Compensation Corporation	http://www.acc.co.nz/index.htm
Scotland	Scottish Intercollegiate Network	http://www.sign.ac.uk
Sweden	Swedish Council on Technology Assessment in Health Care	http://www.sbu.se
UK	National Library of Guidelines	http://www.library.nhs.uk/guidelinesfinder
USA	National Institutes of Health Consensus Development Program	http://consensus.nih.gov
	National Guideline Clearinghouse	http://www.guideline.gov
	Agency for Healthcare research & Quality	http://www.ahrq.gov/

Finally, the computerized searches were supplemented by hand searches of the bibliographies of key articles (particularly systematic reviews and guidelines) and with articles submitted by interested parties.

Articles chosen for analysis were then assessed for their quality using criteria that were appropriate to the study type.

For systematic reviews, the quality criteria chosen were:

1. Study Identification	
Multiple electronic databases	
Unbiased explicit searching strategies	
Hand searches	
Attempts to include "gray" literature	
Estimation of potential publication bias	
2. Study selection	
Only randomized controlled trials included	
Explicit inclusion/exclusion criteria	
Selection criteria applied uniformly	
Rationale for excluding studies	
3. Appraisal of studies	
Described in detail	
Uniformly applied to all studies	
Important parameters addressed	
<ul style="list-style-type: none"> • random allocation • double blinding • relevant outcome measures • follow-up of at least 80 per cent of participants • analysis consistent with the study design 	_____ _____ _____ _____ _____
Effect of study quality on conclusions assessed	
4. Data Collection	
Was missing information considered?	
5. Data synthesis	
Assessment for heterogeneity	
All valid studies used	
Sensitivity analysis performed	
Variations between studies considered	

For randomized controlled trials, the quality criteria were:

Random allocation	
Minimal dropouts (< 15%)	
Blinding of patient	
Blinding of the assessor	
Co-treatments have been used in an equivalent manner among treatment groups.	
Assessment of the extent of patient adherence to the prescribed therapy	
No unintended crossovers from one study treatment to the other.	
Adequate consideration of statistical and clinical significance of findings.	
Adequate demographic description of patients, including at least age, gender, and referral source.	
Adequate clinical description, including pain duration, neurologic deficits, sciatica, previous surgery, and other inclusion or exclusion criteria.	
Adequate description of treatment in terms of dosage, duration, frequency, and technique.	
Reporting of all relevant outcomes, which may include symptoms, physiologic changes, functional ability, costs of care, and psychological measures.	

These criteria were adapted from recommendations for critical appraisal of systematic reviews and randomized controlled trials found in the peer-reviewed literature and textbooks of evidence-based medicine.⁵

For guidelines, the quality criteria were derived from the instrument developed by The AGREE Collaboration started in 1998 as a research project under the Biomedicine and Health Research (BIOMED 2) Programme, funded by the European Union⁶:

Scope and purpose	
Objective(s) of the guideline are specifically described.	
The clinical question(s) is specifically described.	
The patients to whom the guideline is meant to apply is specifically described.	
Stakeholder involvement	
The guideline development group includes individuals from all the relevant professional groups.	
The patients' views and preferences are sought.	
Rigour of development	
Systematic methods are used to search for evidence.	
The criteria for selecting the evidence are clearly described.	
The methods used for formulating the recommendations are clearly described.	
The health benefits, side effects and risks are considered in formulating the recommendations.	
There is an explicit link between the recommendations and the supporting evidence.	
The guideline was externally reviewed by experts prior to publication.	
A procedure for updating the guideline is provided.	
Clarity and presentation	
The recommendations are specific and unambiguous.	
The different options for diagnosis and/or treatment of the condition are clearly presented.	
Key recommendations are easily identifiable.	
Applicability	
The target users of the guideline are clearly defined.	
The potential organizational barriers in applying the recommendations are discussed.	
The potential cost implications of applying the recommendations were considered.	
The guideline is supported with tools for application.	
The guideline presents key review criteria for monitoring and audit purposes	
The guideline was piloted among end users.	
Editorial independence	
The guideline is editorially independent from the funding body.	
Conflicts of interest of guideline development members are recorded.	

Articles were scored "yes", "no", "can't tell" on each item. A summary score was determined by adding together the "yes" responses, dividing by the total number of criteria. This scoring system is a short hand way of indicating overall study quality and is similar to systems used in many systematic reviews for evaluating primary source literature.

⁵ Oxman AD, Cook DJ, Guyatt GH "Users' guides to the medical literature. VI How to use an overview" *Journal of the American Medical Association* 1994; 272(17): 1367-1371

Guyatt GH, Sackett DL, Cook DJ "Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid?" *Journal of the American Medical Association* 1993; 270(21): 2598-601.

Crombie IK *The Pocket Guide to Critical Appraisal: A Handbook for Healthcare Professionals* London; BMJ Publishing Group, 1996

⁶ <http://www.agreecollaboration.org/>

In addition, the author's conclusions regarding spinal cord stimulator were abstracted, and, in the case of the systematic reviews, the primary literature relied upon by the author(s) in reaching their conclusions was identified and tabulated. The results of the quality review, the author's conclusions, and, if relevant, the bibliography of the primary source literature were entered into a "Summary Sheet" for each article. These Summary Sheets were then also hyperlinked to the Department database.

Finally, the abstracted conclusions from each article were transferred to a separate spreadsheet. There, the conclusions were first sorted onto different pages based on the clinical population addressed in the study (Failed back Surgery Syndrome (and other spinal pain problems), Complex Regional Pain Syndrome, and Mixed Chronic Pain Patients); then they were arranged thematically into columns for comparison across articles.

Results

The first PubMed search used a search string published in the medical literature that has been validated as both sensitive and specific for retrieving systematic reviews.⁷ The search string was combined first with the key words "spinal cord stimulator" and "neurostimulator." Because a search done limiting articles to those published since 1990 yielded less than 10 unique references, this search was expanded to the entire Pub Med database. Expanding this search to the entire PubMed database still did not yield more than 10 unique references, so the search was eventually expanded to include other types of articles. Separate searches were done for articles reporting on the use of spinal cord stimulator in low back pain patients and in patients with complex regional pain syndrome (reflex sympathetic dystrophy). The results of the searches can be found in the documents "SCS and LBP.doc", "SCS and RSD.doc", "Neurostim and LBP.Doc", "Neurostim and RSD.Doc", "SCS-CT.doc", "SCS-meta_analysis.doc", and "SCS-RCT.doc" (Available at: <http://www.doli.state.mn.us/msrb/scs/>).

These searches retrieved 161 titles, some found more than once. Of these, 63 articles were presumed relevant based on their title and retrieved for further review.

The searches of the Cochrane Database of Systematic Reviews (CDSR) of the Database of Abstracts of Reviews of Effects (DARE) were done using the key word "spinal cord stimulator" and did not yield any new references not found in the PubMed search.

The hand search added 4 articles which were considered potentially relevant (their ID# marked with a suffix "h" in the database) and 2 articles were submitted by interested parties (their ID# marked with a suffix "s" in the database).

⁷ " ((meta-analysis [pt] OR meta-analysis [tw] OR metanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw]))) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti])) BUTNOT (case* [ti] OR report [ti] OR editorial [pt] OR comment [pt] OR letter [pt]) " found in Shojania KG, Bero LA. "Taking advantage of the explosion of systematic reviews: an efficient MEDLINE search strategy" *Eff Clin Pract* 2001;4(4): 157-62.

The search for guidelines on the World Wide Web found 9 and another was submitted by an interested party.

References for all the articles chosen for further review were combined in an Excel database, spinal-stim.xls (see Appendix 3). Of the 79 articles (9 systematic reviews, 6 randomized controlled trials, 12 guidelines, 3 clinical trials, 6 economic evaluations, 11 unsystematic reviews/editorials, and 32 case series/studies), the full article was available electronically for 44 of them through the Lumina portal at the University of Minnesota (9 systematic reviews, 5 randomized controlled trials, 2 guidelines, 2 clinical trials, 6 economic evaluations, 6 unsystematic reviews/editorials, and 14 case series/studies). Ten guidelines were available through the World Wide Web or were made available by an interested party. When available, the full article was hyperlinked to the database. The article's abstract was then reviewed to determine level of evidence and the relevance of the article.

In all, 14 articles met the inclusion criteria (9 systematic reviews, 5 randomized controlled trials, 12 guidelines) and were entered into a second Excel database, spinal stim - review.xls (see Appendix 4). A quality review was then performed for each article.

The retrieved articles varied in quality. The systematic reviews had summary quality scores ranging from 5/22 to 20/22. However, 5 of the 7 systematic reviews had quality scores greater than 15/22. The randomized controlled trials had summary quality scores ranging from 8/12 to 10/12. The guidelines had summary quality scores ranging from 7/23 to 20/23; however, 5 had scores greater than 13/23.

Overall, all of the systematic reviews and RCTs addressed the question of effectiveness. Five of the systematic reviews and three of the RCTs addressed issues of safety. Two systematic reviews focused on the use of spinal cord stimulators in patients with low back pain, two focused on their use in patients with complex regional pain syndrome (reflex sympathetic dystrophy) and five assessed the effectiveness of spinal cord stimulators in general. Two RCTs included only patients with low back pain and the others included only patients with complex regional pain syndrome (reflex sympathetic dystrophy). Five of the systematic reviews reported on the criteria used for judging whether a patient had a favorable response during a trial period; four reported on the appropriate trial period.

Three of the guidelines were specific to the use of spinal cord stimulators in patients with complex regional pain syndrome (reflex sympathetic dystrophy); one addressed only use in patients with failed back surgery syndrome, while three addressed their use in chronic pain patients without concern for the underlying condition. The others provided guidance regarding both complex regional pain syndrome (reflex sympathetic dystrophy and failed back surgery syndrome cases. The evidence used in developing the recommendations was referenced in the available text for 10 of the 12 guidelines. Those guidelines all relied, at least in part, on systematic reviews and RCTs; in most cases those systematic reviews and RCTs were the same ones identified in the searches done for this report (as noted in columns K and L of spinal stim - review.xls).

The conclusions made by the article's author(s) were then abstracted and entered into a third database, spinal stim - analysis.xls (see Appendix 4). There, the conclusions were first sorted onto different pages based on the clinical population addressed in the study (Failed back Surgery Syndrome (and other spinal pain problems), Complex Regional Pain Syndrome, and Mixed Chronic Pain Patients); then they were arranged thematically into columns for comparison across articles. Themes were identified inductively from the abstracted conclusions by arranging them into the fewest mutually exclusive categories.

The themes identified were:

<i>theme</i>	<i># articles</i>	<i>summary quality scores</i>
Sources of data	SysRev: 9 RCT: 5 Guidelines: 10	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 7/23 – 20/23
Comments on data	SysRev: 7 RCT: 5 Guidelines: 10	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 7/23 – 20/23
Quantitative results	SysRev: 9 RCT: 5 Guidelines: 6	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 10/23 – 20/23
Reported complications	SysRev: 6 RCT: 4 Guidelines: 1	SysRev: 5/22 – 18/22 RCT: 9/12 – 10/12 Guidelines: 14/23
Study design issues	SysRev: 7 RCT: 5 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12
Author's overall conclusions	SysRev: 8 RCT: 5 Guidelines: 11	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12 Guidelines: 10/23 – 20/23
Comments on length of trial period	SysRev: 3 RCT: 1 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 10/12
Comments on judging trial success	SysRev: 3 RCT: 5 Guidelines: 0	SysRev: 5/22 – 20/22 RCT: 8/12 – 10/12

Conclusions

The Department found considerable agreement of published opinion on each issue. While the individual articles varied in quality, this variation does not significantly affect the conclusions reached by the authors. Articles of higher quality most often reached the same conclusions as those of lower quality.

Nine of the 12 guidelines recommended the use of spinal cord stimulation in at least some clinical situations (5 of 6 guidelines with recommendations for back pain patients; 7 of 8 guidelines with recommendations for complex regional pain syndrome patients; 2 of 3 guidelines for recommendations for chronic pain patients in general).⁸ The guidelines not recommending

⁸ Some guidelines had recommendations for more than one clinical situation.

the use of spinal cord stimulators did not differ markedly in quality from those recommending their use but did tend to rely on a smaller base of data.

The conclusions drawn by the Department from the reviewed literature are:

1. There is limited evidence (predominantly from case series and two RCTs) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 60% of patients with chronic spinal conditions who have a positive response during a screening trial period.

<i>reference</i>	<i>author's conclusions</i>
<u>Neurosurgery. 1995 Dec;37(6):1088-95</u>	In sum, approximately 50 to 60% of patients with FBSS report \geq 50% pain relief with SCS.
<u>Spine. 2005 Jan 1;30(1):152-60</u>	The level of evidence for the efficacy of SCS in patients with CLBP/FBSS remains "moderate." The greatest level of pain relief following SCS appeared to be associated with case series that were of poor quality, short follow-up duration, undertaken in a multicenter setting, and that recruited patients with CLBP or FBSS specifically.
<u>Neurosurgery. 2005;56(1):98-106</u>	This prospective, randomized trial confirms the inference from previous studies that SCS is superior to reoperation in patients with persistent radicular pain after lumbosacral spine surgery. In patients with persistent radicular pain after lumbosacral spine surgery, therefore, our findings indicate that clinicians should offer SCS as an alternative to repeated operation before exhausting all surgical alternatives.
<u>Pain xxx (2007) xxx-xxx</u>	The favorable effect of SCS on neuropathic pain is consistent with the results of previously reported trials.
<u>Eur Spine J 2006; 15:S192-S300</u>	We cannot recommend the use of spinal cord stimulation for the treatment of chronic nonspecific LBP.
<u>Assessment and management of chronic pain.</u>	Patients with lumbar and cervical radiculopathy who are not surgical candidates, and patients with postlaminectomy syndrome are the best candidates for SCS.
<u>Considered Judgment Form: Neuromodulation-Spinal Cord Stimulation</u>	We do not recommend spinal cord stimulation for the treatment of adults with pain due to failed back surgery syndrome.
<u>Treatment in Workers' Compensation 2006</u>	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
<u>J Neurosurg 2004; 100:S254-S67</u>	There is some evidence to indicate that SCS has positive, symptomatic, long-term effects on ... failed-back surgery syndrome pain.
<u>Cochrane Database Syst Rev. 2004;(3):CD003783</u>	At the present time there is limited evidence that spinal cord stimulators are effective for some types of chronic pain (FBSS ...).
<u>J Pain Symptom Manage 2004; 27:370-378</u>	SCS is economically favorable in comparison to other therapies for patients with FBSS... The initial acquisition costs of SCS appear to be offset by a reduction in healthcare resources, such as drug therapy, physician visits, and hospitalization episodes.
<u>Spinal cord stimulation for the management of pain: recommendations for best clinical practice</u>	For indications strongly supported by evidence, i.e. ..., neuropathic pain following spinal surgery..., SCS should be considered early in the patient's management when simple first line therapies have failed. SCS should not necessarily be considered a treatment of last resort.
<u>Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients</u>	Do not recommend using spinal cord stimulators with chronic pain patients.
<u>Summary and Conclusions of the SBU Report on: Methods of Treating Chronic Pain. A Systematic Review</u>	Spinal cord stimulation has been shown to reduce ... low back (Evidence Grade 2) pain.

2. There is limited evidence (predominantly from case series and one RCT) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 67% of patients with complex regional pain syndrome (reflex sympathetic dystrophy) who have a positive response during a screening trial period.

<i>reference</i>	<i>author's conclusions</i>
<u>Clin J Pain. 2003 Nov-Dec;19(6):371-83</u>	We conclude that available evidence suggests that SCS is effective for

	the management of pain for patients with CRPS who did not respond to more conservative medical management (grade B/C).
<u>Eur J Pain 2006 10(2) 91-101</u>	SCS appears to be an effective therapy in the management of patients with CRPS type I (Level A evidence) and type CRPS II (Level D evidence). Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS type I.
<u>N Engl J Med. 2000 Aug 31;343(9):618-24</u>	In carefully selected patients with chronic reflex sympathetic dystrophy, electrical stimulation of the spinal cord can reduce pain and improve health-related quality of life.
<u>Ann Neurol. 2004 Jan;55(1):13-8</u>	We conclude that after careful selection and successful test stimulation SCS is safe and has long-term effectiveness in reducing pain.
<u>N Engl J Med. 2006 Jun 1;354(22):2394-6</u>	The pain-alleviating effect of SCS in CRPS diminishes with time, and is no longer statistically significant after 3 years.
<u>Spinal Cord Stimulation. Use in Patients with Complex Regional Pain Syndrome</u>	Incorporating the lack of high level medical research on this subject, along with its significant potential adverse effect rate and poor compensation outcome measures when SCS are used, the WCB should continue with its present position of not authorizing its use in the injured worker population.
<u>Eur J Neurol 2007; 14:952-970</u>	Level B evidence for effectiveness of SCS in CRPS I
<u>Assessment and management of chronic pain.</u>	Patients with complex regional pain syndrome (CRPS) type I or (RSD) are the best candidates for SCS.
<u>Considered Judgment Form: Neuromodulation-Spinal Cord Stimulation</u>	We recommend spinal cord stimulation should be used in highly selected patients with complex regional pain syndrome type I.
<u>Complex Regional Pain Syndrome type I Guidelines</u>	Pain control with spinal cord stimulation is a responsible choice for carefully selected CRPS-I patients who have not responded to other treatments.
<u>Treatment in Workers' Compensation 2006</u>	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
<u>Evidence Based Review. Spinal Cord Stimulation</u>	There is no quality evidence that SCS is superior treatment long term especially when a cost/benefit perspective is required
<u>J Neurosurg 2004; 100:S254-S67</u>	There is some evidence to indicate that SCS has positive, symptomatic, long-term effects on CRPS I and II ...
<u>Cochrane Database Syst Rev. 2004;(3):CD003783</u>	At the present time there is limited evidence that spinal cord stimulators are effective for some types of chronic pain (... CRPS Type 1).
<u>J Pain Symptom Manage 2004; 27:370-378</u>	SCS is economically favorable in comparison to other therapies for patients with ... CRPS. The initial acquisition costs of SCS appear to be offset by a reduction in healthcare resources, such as drug therapy, physician visits, and hospitalization episodes.
<u>Spinal cord stimulation for the management of pain: recommendations for best clinical practice</u>	For indications strongly supported by evidence, i.e. CRPS, ... SCS should be considered early in the patient's management when simple first line therapies have failed. SCS should not necessarily be considered a treatment of last resort.
<u>Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients</u>	Do not recommend using spinal cord stimulators with chronic pain patients.
<u>Summary and Conclusions of the SBU Report on: Methods of Treating Chronic Pain. A Systematic Review</u>	Spinal cord stimulation has been shown to reduce peripheral neuropathic (Evidence Grade 3) ... pain. Notwithstanding high initial expenses, spinal cord stimulation combined with physical therapy is cost-effective in treating neuropathic pain (Evidence Grade 3).

3. There is inconsistent evidence as to whether spinal cord stimulators improve other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).

<u>reference</u>	<u>author's conclusions</u>
<u>Neurosurgerv. 1995 Dec;37(6):1088-95</u>	However, there is insufficient evidence to draw conclusions ... about the effects of SCS on patient work status, functional disability, and health care and medication use.
<u>Clin J Pain. 2003 Nov-Dec;19(6):371-83</u>	Definitive conclusions cannot be made with regard to any of the secondary outcome measures, in part due to poor methodological design and in part due to inadequate reporting by the authors.
<u>Spinal Cord Stimulation. Use in Patients with Complex Regional Pain Syndrome</u>	Incorporating the lack of high level medical research on this subject, along with its significant potential adverse effect rate and poor compensation outcome measures when SCS are used, the WCB should continue with its present position of not authorizing its use in the

	injured worker population.
<u>Pain. 2004 Mar;108(1-2):137-47</u>	We conclude that the literature on SCS for FBSS ... remains inadequate to make definitive statements about efficacy in reducing physical disability, work disability, and medication consumption.

4. There is inconsistent evidence as to whether spinal cord stimulators are more effective than alternatives for relieving pain in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).

<i>reference</i>	<i>author's conclusions</i>
<u>Neurosurgerv. 1995 Dec;37(6):1088-95</u>	No conclusions may be drawn concerning the efficacy of SCS for FBSS relative to other treatments, placebo treatments, or no treatment.
<u>N Engl J Med. 2006 Jun 1;354(22):2394-6</u>	The pain-alleviating effect of SCS in CRPS diminishes with time, and is no longer statistically significant after 3 years.
<u>Complex Regional Pain Syndrome type I Guidelines</u>	Pain control with spinal cord stimulation is a responsible choice for carefully selected CRPS-I patients who have not responded to other treatments.
<u>Treatment in Workers' Compensation 2006</u>	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
<u>Evidence Based Review. Spinal Cord Stimulation</u>	There is no quality evidence that SCS is superior treatment long term especially when a cost/benefit perspective is required
<u>Pain. 2004 Mar;108(1-2):137-47</u>	Using recently published criteria for levels of evidence, there is moderate evidence (one high-quality RCT) that SCS plus PT is more effective than PT-only for patients with CRPS type I in relieving pain at 6- and 12-month follow-ups. Both the RCT and lower-quality studies suggest a modest pain-relieving effect on average. Less regarding comparisons with placebo controls, other treatments, or the natural history can be gleaned from the literature.

5. Complications occur in 1/3 to 1/2 of cases, but are often mild and mostly involving problems with the equipment or local infection. But up to 1/3 of patients will require re-operation in the first two years due to complications.

<i>reference</i>	<i>complications</i>
<u>Neurosurgerv. 1995 Dec;37(6):1088-95</u>	<ul style="list-style-type: none"> o 13 studies: 42% (range 20-75%) of patients had some kind of complication. o 20 studies: 5% (range 0-12%) of patients had an infection. o 17 studies: 9% (range 0-42%) of patients had a biological complication other than infection. o 13 studies: 30% (range, 0-75%) of patients had one or more stimulator-related complications.
<u>Spine. 2005 Jan 1;30(1):152-60</u>	<ul style="list-style-type: none"> o <u>RCT</u>: Four (17%) and six (26%) patients with FBSS experienced complications at 6 and 12 months post SCS implantation, respectively. o <u>Case Series</u>: Overall, 43% of patients with CBLP/FBSS experienced one or more complications with SCS. The majority of these complications were due to electrode or lead problems (195/722; 27%). Infections (6%), generator problems (6%), extension cable problems (10%), or other issues, such as cerebrospinal fluid leaks (7%), accounted for the remainder.
<u>Neurosurgerv. 2005;56(1):98-106</u>	One SCS patient developed an infection at the receiver site, which was treated by removal of the system followed by specific antibiotic therapy. The system was replaced without further complication. Three SCS patients (9% of permanent implants) underwent hardware revisions because of technical problems (electrode migration or malposition).
<u>Pain xxx (2007) xxx-xxx</u>	Of 84 patients, 27 (32%) experienced a total of 40 device-related complications. For 20 patients (24%), surgery was required to resolve the event. Principal complications were electrode migration (10%), infection or wound breakdown (8%), and loss of paresthesia (7%).
<u>Pain Physician. 2007 Jan;10(1):7-111</u>	Complications with spinal cord stimulation range from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage,

	paralysis, nerve injury, and death.
<u>Clin J Pain. 2003 Nov-Dec;19(6):371-83</u>	<ul style="list-style-type: none"> o The proportion of patients with at least one complication ranged from 9% to 50%. o The infection rate ranged from 1.4% to 11.1%. o The rate of complication due to technical problems such as equipment failure, lead migration, or lost coverage ranged from 8.3% to 42.8%. o The rate of reoperation ranged from 11.1% to 50%.
<u>Eur J Pain 2006 10(2) 91-101</u>	<ul style="list-style-type: none"> o <u>RCT</u>: Six of the 36 patients receiving SCS plus physical therapy experienced complications (n = 11) at 6 months but only one complication (infection) was reported at 12 months. A total of 9 of the 24 patients (38%) experienced 22 complications needing operation during the 2-years after implantation. o <u>Case Series</u>: Overall, in eight studies, 33.0% (22/66) of patients reported at least one complication with SCS. The majority of complications were related to electrode issues (20% of patients), infections (4% of patients), generator issues (2% of patients) or extension cable issues (1%) of patients. A further 6% of patients had other complications such as hematomas.
<u>N Engl J Med. 2000 Aug 31;343(9):618-24</u>	Six of the 24 patients had complications that required additional procedures, including removal of the device in 1 patient.
<u>Ann Neurol. 2004 Jan;55(1):13-8</u>	Four of the six had long term complications.
<u>Pain Physician. 2007 Jan;10(1):7-111</u>	<ul style="list-style-type: none"> o 9 of 24 patients (38%) suffered 22 complications needing operation during the 2 years after implantation. o The most frequent complications were electrode displacement and pain from the pulse generator pocket. o Two patients underwent permanent removal of the system on the grounds of recurrent rejection and relapsing ulcerative colitis subscribed to the system, respectively o Side effects were reported by all 22 patients who still had an implanted system at 2 years.
<u>J Neurosurg 2004; 100:S254-S67</u>	Complications with spinal cord stimulation range from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.
<u>J Neurosurg 2004; 100:S254-S67</u>	Most complications were not life threatening and could usually be resolved by removing the device. The most common complication was lead migration. The most serious complication was paralysis
<u>Pain. 2004 Mar;108(1-2):137-47</u>	18 articles: average of 34% (range 0–81%) of the patients who received a permanent stimulator had one or more undesirable outcomes during the study follow-up period. These included superficial and deep infections, local pain in the region of stimulator components, biological complications other than infection or local pain (e.g. dural puncture), equipment failure, a stimulator revision (additional operation to correct an equipment problem; we did not include battery changes in this category), and stimulator removal (most commonly because of infection, equipment failure, or lack of pain relief). Removals included both permanent removals and removals followed by eventual re-implantations (e.g. removal due to infection and stimulator implantation after resolution of the infection).

6. Trial screening periods in the reported case series and clinical trials have lasted from 1 day up to 30 days, with most lasting from 3 to 7 days. There is no information to judge whether the length of the trial period influences the reported efficacy of spinal cord stimulation.

<u>reference</u>	<u>trial period</u>
<u>Neurosurgery. 1995 Dec;37(6):1088-95</u>	In 34 studies, there were temporary electrode trials, lasting 1 to 3 days in 4 studies, 4 to 7 days in 8 studies, 8 to 14 days in 4 studies, and more than 2 weeks in 2 studies. The length of the trial considerably varied across patients in 1 study and was not specified in 15 studies.
<u>Neurosurgery. 2005;56(1):98-106</u>	SCS treatment began with percutaneous placement of a temporary electrode for a therapeutic trial lasting at least 3 days.
<u>Clin J Pain. 2003 Nov-Dec;19(6):371-83</u>	Eleven studies reported the duration of the stimulation trial period that ranged from 3 to 30 days. Six of these studies reported trial stimulation

	that lasted 7 days or less. The remaining 5 studies reported trial stimulation of greater than 7 days.
<u>Cochrane Database Syst Rev. 2004;(3):CD003783</u>	1 of 2 studies: Percutaneous placement of a temporary electrode for routine 2- 1/2 day trial.

7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.

<i>reference</i>	<i>trial success</i>
<u>Neurosurgerv. 1995 Dec;37(6):1088-95</u>	In the 34 studies in which patients were screened with temporary electrodes to determine suitability for permanent implants, the criteria for permanent implants were specifically stated to be pain relief in 19 studies, region of paresthesia in 8 studies, decreased medication use in 2 studies, and increased activity in 2 studies. Only eight articles stated a threshold percentage of pain relief for permanent implantation, and across these studies, the minimum percent pain relief for implantation ranged from 30 to 75% (30% in one study, 50% in five, 70% in one, and 75% in one).
<u>Neurosurgerv. 2005;56(1):98-106</u>	The SCS patients could receive a permanent implant if they reported at least 50% estimated relief of pain by standard pain rating methods and demonstrated stable or improved analgesic medication intake, with improved physical activity commensurate with neurological status and age.
<u>Pain xxx (2007) xxx-xxx</u>	Criteria for implanting SCS: at least 80% overlap of pain distribution with stimulation-induced paresthesia and at least 50% leg pain relief.
<u>Clin J Pain. 2003 Nov-Dec;19(6):371-83</u>	There was considerable variability in the criteria used to determine successful trial stimulation. Quantitative and validated measures of pain relief were not used by all studies to determine trial success. A 50% decrease in VAS score for pain or a rating of 6 on the global perceived effect (GPE) scale was necessary to define success in 2 studies. Three studies used 50% pain relief from baseline VAS scores, while 1 study used walking distance along with 70% pain relief as the primary outcome measure. Other studies used nonspecific outcomes such as "patient satisfied", "acceptable degree of analgesia", "patient benefited", or "pain relief to avoid heavy analgesic use."
<u>N Engl J Med. 2000 Aug 31;343(9):618-24</u>	The decision to implant the permanent SCS system was made when pain intensity during the testing period was at least 50% lower as compared with the original (baseline) visual analog score, or if "much improvement" was reported on a seven-point global perceived effect scale.
<u>Cochrane Database Syst Rev. 2004;(3):CD003783</u>	1 of 2 studies: If a patient reports at least 50% estimated relief of pain, while demonstrated stable or improved medication intake, and improved physical activity commensurate with neurologic status and age, a permanent implant was offered.

Recommendations

Based on the conclusions derived from the literature the Department proposes the following draft recommendations to the Medical Services Review Board, to be used as the basis for changes to the Permanent Treatment Parameters governing the use of spinal cord stimulators in workers' compensation claims.

I. Spinal cord stimulators can effectively relieve pain in some patients with chronic spinal pain or complex regional pain syndrome (reflex sympathetic dystrophy).

II. An adequate trial period of at least three days is needed to determine who might benefit from spinal cord stimulation.

III. Adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from spinal cord stimulation.

Appendix 1

The Department's website for this project is: <http://www.doli.state.mn.us/msrb/scs/>

All of the Department's work products are available on the website.

Appendix 2

The Word files “SCS and LBP.doc”, “SCS and RSD.doc”, “Neurostim and LBP.Doc”, and “Neurostim and RSD.Doc”, “SCS-CT.doc”, “SCS-meta_analysis.doc”, “SCS-RCT.doc” (Available at: <http://www.doli.state.mn.us/msrb/scs/>) list all of the articles found in the literature searches.

Appendix 3

The Excel workbook [spinal-stim.xls](#) (Available at: <http://www.doli.state.mn.us/msrb/scs/>) lists all of the articles that were selected by the Department for further review.

Column A is an ID number

Column B lists the authors of the article.

Column C is the title of the article.

Column D gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column E identifies the type of article:

“SysRev” is a systematic review,

“RCT” is a randomized controlled trial

“CT” is a nonrandomized trial

“CE” is an economic evaluation

“Guide” is an evidence-based treatment guideline

“Review” is an unsystematic review

“Editorial” is a statement of a single physician’s opinion

“CaseSer” is a case series

“CaseRep” is a single case report

Column F indicates whether the article was determined to be relevant for the purposes of this study based on the levels of evidence hierarchy.

Column G indicates the availability of the article.

Column H indicates the patient subgroup(s) discussed in the article.

Appendix 4

The Excel workbook [spinal stim - review.xls](#) (Available at: <http://www.doli.state.mn.us/msrb/scs/>) lists the results of the quality review of the articles that were selected by the Department for this analysis.

Column A is an ID number

Column B lists the authors of the article.

Column C gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column D identifies the type of article:

“SysRev” is a systematic review,

“RCT” is a randomized controlled trial

“Guide” is an evidence-based treatment guideline.

Column E is marked with an “X” if the article discusses efficacy.

Column F is marked with an “X” if the article discusses safety.

Column G indicates the patient subgroup(s) discussed in the article.

Column H is a hyperlink to the summary sheet for the article

Column I is the summary quality score of the article

Column J includes any comments about the article

For guidelines only:

Column K lists the ID# for any systematic reviews included in this analysis that were used by the authors of the guideline.

Column L lists the ID# for any randomized clinical trials included in this analysis that were used by the authors of the guideline.

Column M lists the ID# for any guidelines included in this analysis that were used by the author's of the guideline.

Appendix 5

The Excel workbook [spinal stim -analysis.xls](#) (available at: <http://www.doli.state.mn.us/msrb/scs/>) lists the author's findings and conclusions regarding the efficacy and safety of spinal cord stimulators, and any other information relevant to the questions posed for this analysis. Wherever possible, the conclusions are stated in the authors' own words.

This workbook has 3 spreadsheets or pages:

The **first page** lists the results for articles that addressed the use of spinal cord stimulators in patients with low back pain.

- Column A** gives the abbreviated citation as found in Medline and is an active link. Clicking on the journal citation will call up the abstract and/or article
- Column B** identifies the type of article: "SR" is a systematic review, "RCT" is a randomized controlled trial, and "Guide" is an evidence-based treatment guideline.
- Column C** lists the sources of information used.
- Column D** lists any comments made by the authors regarding the sources of information.
- Column E** lists the quantitative results of the study.
- Column F** lists any information regarding complications.
- Column G** lists any comments made by the authors regarding the study design or other methodological issues.
- Column H** lists the authors' overall conclusions on the use of spinal cord stimulation.
- Column I** is intentionally blank.
- Column J** lists any information given regarding the conduct of a trial period.
- Column K** lists any information given regarding the criteria for judging a trial as successful.

The **second page** lists the results for articles that addressed the use of spinal cord stimulators in patients with complex regional pain syndrome.

- Column A** gives the abbreviated citation as found in Medline and is an active link. Clicking on the journal citation will call up the abstract and/or article
- Column B** identifies the type of article: "SR" is a systematic review, "RCT" is a randomized controlled trial, and "Guide" is an evidence-based treatment guideline.
- Column C** lists the sources of information used.
- Column D** lists any comments made by the authors regarding the sources of information.
- Column E** lists the quantitative results of the study.
- Column F** lists any information regarding complications.
- Column G** lists any comments made by the authors regarding the study design or other methodological issues.
- Column H** lists the authors' overall conclusions on the use of spinal cord stimulation.
- Column I** is intentionally blank.
- Column J** lists any information given regarding the conduct of a trial period.
- Column K** lists any information given regarding the criteria for judging a trial as successful.

The **third page** lists the results for articles that addressed the use of spinal cord stimulators in chronic pain patients in general.

Column A gives the abbreviated citation as found in Medline and is an active link.

Clicking on the journal citation will call up the abstract and/or article

Column B identifies the type of article: “SR” is a systematic review, “RCT” is a randomized controlled trial, and “Guide” is an evidence-based treatment guideline.

Column C lists the sources of information used.

Column D lists any comments made by the authors regarding the sources of information.

Column E lists the quantitative results of the study.

Column F lists any information regarding complications.

Column G lists any comments made by the authors regarding the study design or other methodological issues.

Column H lists the authors’ overall conclusions on the use of spinal cord stimulation.

Column I is intentionally blank.

Column J lists any information given regarding the conduct of a trial period.

Column K lists any information given regarding the criteria for judging a trial as successful.

Appendix 6

The Excel workbook spinal stim –primary sources.xls (available at: <http://www.doli.state.mn.us/msrb/scs/>) lists all of the original studies referenced by the authors of systematic reviews and evidence-based guidelines.