



Medical Services Review Board

April 19, 2012

Minutes

Members present

Aysel Atli, M.D.
Beth Baker, M.D.
Jeffrey Bonsell, D.C.
Russell Gelfman, M.D.
Michael Goertz, M.D.
John Kipp, M.D., J.D.
Rose Hatmaker
Kimberly Olson
Reed Pollack
James Samuelson
Cally Theisen, M.D., D.P.M.
Dan Wolfe, P.T., G.D.M.T.

Members absent

Glenda Cartney, R.N.
Lisa Hanselman, OTR/L
Kathi Henrickson, R.N.
Greg Hynan, D.C.
Brian Konowalchuk, M.D., M.P.H.
Jody Ruppert, OTR/L
Robin Peterson, P.T.
Andrew Schmidt, M.D.
Margaret Spartz, M.D.

Staff members present

Kate Berger
Deputy Commissioner Kris Eiden
Wendy Legge
William Lohman, M.D.
Pamela McLaughlin
Jessica Stimac
Lisa Wichterman
Laura Zajac

Visitors present

Cristine Almeida, Almeida, P.A.
Dawn Carlson, Almeida, P.A.
Sherri Giorgio, Medtronic - *via phone*
Susan Giguere, MAPS
Liesl Hargens, Medtronic
Heather Keenan, MAPS
Anne Thompson, Medtronic
Daniel Wulff, MNAJ

Call to order and introductions

The meeting was called to order by Chairwoman Dr. Beth Baker. Announcements were made. Introductions were made. A quorum was met.

Approval of the minutes and agenda

Minutes from the Jan. 19, 2012, meeting were approved with the addition of Rose Hatmaker to the list of attendees. The April 19, 2012, agenda was approved.

Announcements and updates

Deputy Commissioner Kris Eiden made announcements about the EOB compliance issue. A story will be published in the *COMPACT* newsletter about what is required for compliance of the rule for EOBs. The biggest offenders of noncompliant EOBs will be contacted to meet with department staff members. Board members were invited to attend the 2012 Workers' Compensation Summit in Brainerd, Minn., June 12 and 13.

Data practices

Wendy Legge gave a presentation about data practices. The presentation reviewed the different types of public, nonpublic and private data. Also presented were the responsibilities that go along with the different types of data.

Spinal stimulators and implantable pumps

Dr. William Lohman reviewed the draft rules for spinal cord stimulators and implantable pain pumps. Changes to the draft are adding a psychological examination to the requirement and a second opinion by a provider outside of the treating physician's practice. This provider could be of any type of specialty. The board discussed whether the rule should state that a physician experienced with pain management should do the second opinion. A majority of the board members expressed they wanted to leave the rule language as presented. The board voted and approved the rule as presented.

Spinal fusion and implants

Lohman presented information about spinal fusion. The presentation included different studies of patients, comparing the results of surgical versus nonsurgical treatments. Guideline comparisons between workers' compensation states Minnesota and Washington, and three general health carriers, were reviewed.

Kim Olson presented a study of lumbar fusion in Minnesota from 2009 to 2011. The study included the number and costs of fusions, broken down by inpatient hospital costs and implant costs. The study included single, multiple and revised lumbar fusion surgery.

The board discussed what the next steps should be, given the data and information presented: Can the manufacturer of the hardware present to the board what types of costs go into the final cost of the hardware? What are the costs to the employee or system if the employee is now PTD due to a failed fusion? Should risk assessments be done and/or what type of conservative care can be done for degenerative disk disease? How is the psychological exam used to determine if surgery should be approved or denied? Cost containment for the hardware is a topic the Workers' Compensation Advisory Council decides for possible legislation. The board would also like to have the medical necessity of discograms.

Draft of 5217 rule revision with the Rehabilitation Review Panel

Laura Zajac reviewed the rule 5217 draft changes for medical and rehabilitation meetings. The board will vote on the rule changes at the next meeting.

Agenda for the July meeting

The agenda for the next meeting should include the 5217 rule changes.

Adjournment

A motion to adjourn the meeting at 6 p.m. was approved.

Respectfully submitted,

Lisa Wichterman

Medical Policy Analyst

Department of Labor and Industry

Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 04/16/12

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 or
17 (2) 12 weeks following arthrodesis.

18
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 and~~ are indicated only if the conditions of subitems (1), (2) and (3) are satisfied. And
25 ~~require a second opinion that confirms that the treatment is indicated and within the parameters~~
26 ~~listed, and a personality or psychosocial evaluation that indicates that the patient is likely to~~
27 ~~benefit from the treatment.~~

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

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

36
37 (2) Before the trial screening is conducted, a second opinion, from a provider outside of
38 the treating provider's practice, must confirm that the patient is an appropriate candidate
39 for spinal cord stimulator and has no contraindications.

40
41 (3) Long term use of a spinal cord stimulator is indicated if the treating health care
42 provider documents that there has been at least a 50% improvement in pain during a trial
43 screening period of at least three days.

44
45 ~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is~~

Intrathecal Drug Delivery Systems
DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 04/16/12

1 not a candidate for any other surgical therapy, and has had a favorable response to a trial
2 screening period.

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

6
7 D. Intrathecal drug delivery systems have very limited application as provided are
8 indicated only if the conditions of subitems (1), (2) and (3) are satisfied.

9 (1) A trial screening period of these devices is indicated only if the treating health care
10 provider determines that:

11 (a) the patient has intractable pain;

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

13 (c) the patient has no psychological contraindications to this treatment. The
14 treating health care provider shall refer the patient for consultation by a
15 psychologist or psychiatrist to assess the patient for psychological
16 contraindications.

17 (2) Before the trial screening is conducted, a second opinion, from a provider outside of
18 the treating provider's practice, must confirm that the patient is an appropriate candidate
19 for an intrathecal drug delivery system and has no contraindications.

20
21 (3) Long term use of a intrathecal drug delivery systems is indicated if the treating health
22 care provider documents that there has been at least a 50% improvement in pain during a
23 trial screening period of at least 24 hours.

Comparison of Techniques

Cochrane Review:

- 4 trials that assessed whether electrical stimulation could enhance fusion
- all used different methods
- results suggest that electrical stimulation does have a modest effect on enhancing fusion
- [but] it is not possible to assess the relative value of different methods of electrical stimulation
- overall, there was no significant effect [on clinical outcome].

Gilman, RJA, Waddell G "Surgery for Degenerative Lumbar Spondylosis: Updated Cochrane Review" Spine 2005; 30:2312-2320

Comparisons of Techniques

SR & MA of 3 RCTs and 6 comparative observational studies:

- moderate-quality evidence that iPLIF has the advantages of higher fusion rate and better restoration of spinal alignment over iPLF.
- No significant differences were identified between iPLIF and iPLF concerning clinical outcome, complication rate, operating time, and blood loss

Zhou Z-J, Zhao F-D, Fang X-G, Zhao X, Fan S-W "Meta-analysis of Instrumented posterior Interbody fusion versus Instrumented posterolateral fusion in the lumbar spine. A review." J Neurosurg Spine 2011; 15:556-510

Comparison of Techniques

- SR of 3 RCTs and 3 COS:
- No conclusion about the clinical benefit of instrumenting a spinal fusion could be made.
- However, there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion.

Martin CR, Owezykzki AT, Rosenfeld HA, Fildes SM, O'Neil J, Wei EK "The Surgical Management of Degenerative Lumbar Spondylosis: A Systematic Review" Spine 2007; 32:1191-1198

Comparison to Alternative Treatment

Cochrane Review:

- at previous review in 1999 there were no RCTs comparing fusion to natural history, placebo, or alternative treatment
- now 2 trials comparing fusion to non-surgical alternative treatment
- trials showed conflicting results

Gilman, RJA, Waddell G "Surgery for Degenerative Lumbar Spondylosis: Updated Cochrane Review" Spine 2005; 30:2312-2320

The Swedish Trial

Lumbar fusion vs. PT N = 294

- low back pain more than leg pain, lasting longer than 2 years, and no evidence of nerve root compression.
- completed a course of conservative treatment that had failed to produce relief
- randomized into four treatment groups: 72 patients had more conservative treatment, and 222 had 1 of three different fusion techniques
- 98% follow-up at 2 years

Fridolfi P, Hagg O, Westberg P, et al. 2001 Volvo award winner in clinical studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicentre randomized controlled trial from the Swedish lumbar spine study group. Spine 2001;26:3331-34.

The Swedish Trial

- independent assessors rated 46% of the surgical group as "excellent" or "good," compared with 18% of the conservative group ($P = 0.0001$)
- more patients who underwent surgery rated their results as "better" or "much better" (63% vs. 29%, $P = 0.0001$)
- patients who underwent surgery had significantly more improvement in pain and disability
- "net back to work rate" was significantly in favor of surgical treatment (36% vs. 13%, $P = 0.002$)
- no significant differences in any outcome among the three surgical groups.

Fridolfi P, Hagg O, Westberg P, et al. 2001 Volvo award winner in clinical studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain. A multicentre randomized controlled trial from the Swedish lumbar spine study group. Spine 2001;26:3331-34.

The Norwegian Trials

Posterolateral fusion with transpedicular screws and postoperative physiotherapy vs. a "rehabilitation" program

- alternative consisted of an educational intervention and a 3-week course of intensive exercise sessions, based on cognitive-behavioral principles
- two series:
 - 64 patients with low back pain longer than 1 year plus disc degeneration at L4/5 and/or L5/S1
 - 60 patients with chronic low back pain more than 1 year after previous discectomy
- 97% follow-up at 1 year
- in both series, there were no significant differences in any of the main outcomes of independent observer rating, patient rating, pain, disability, or return to work

Bratt J, Svensson B, Filler A, et al. Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercise in patients with chronic low back pain and disc degeneration. Spine 2003;28:1913-21.
Koller A, Bratt J, Gustavson R, et al. Trunk muscle strength, cross-sectional area and density in patients with chronic low back pain randomized to lumbar fusion or cognitive intervention and exercise. Spine 2004;29:3-8.

Comparison to Alternative Treatment

SR of 4 RCTs-

- low back pain for 12 months or longer without a specific diagnosis
- all 4 excluded patients with prior lumbar fusion, but 3 allowed prior laminectomy or discectomy
- variety of fusion techniques between and within studies
- variety of non-surgical treatments in control groups

Mirza SK, Deyo RA "Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Non-operative Care for Treatment of Chronic Back Pain" Spine 2007; 32:816-823

Comparison to Alternative Treatment

- in all 3 trials that used a structured rehabilitation program incorporating cognitive-behavior therapy, improvement in the ODI score was similar in magnitude to the improvement seen with surgery
- surgery may be more efficacious than unstructured nonsurgical care for chronic back pain but may not be more efficacious than structured cognitive-behavior therapy.
- methodological limitations of the randomized trials prevent firm conclusions.

Mirza SK, Deyo RA "Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Non-operative Care for Treatment of Chronic Back Pain" Spine 2007; 32:816-823

Comparison to Alternative Treatment

Table 5. Comparison of the Secondary Outcomes

	Study							
	Fitzlin et al ²⁷		Bren et al ¹⁸ (2003)		Farrar et al ²⁸		Bren et al ¹⁸ (2004)	
	Surg	Nonop	Surg	Nonop	Surg	Nonop	Surg	Nonop
Patient satisfaction of success	62%	25%	25%	17%	N/R	N/R	N/R	N/R
Independent observer rating	42%	18%	24%	22%	N/R	N/R	N/R	N/R
Work satisfaction	12%	20%	5%	6%	N/R	N/R	1%	14%
Work, total	47%	23%	5%	3%	N/R	N/R	10%	22%
Complication rate	1%	0%	10%	0%	1%	2%	0%	0%
Cost-over ratio								
Surgery vs no surgery	n = 12 (1%)		n = 3 (1%)		n = 27 (10%)		n = 5 (2%)	
No surgery vs surgery	n = 2 (1%)		n = 0 (0%)		n = 4 (2%)		n = 1 (1%)	

Mirza SK, Deyo RA "Systematic Review of Randomized Trials Comparing Lumbar Fusion Surgery to Non-operative Care for Treatment of Chronic Back Pain" Spine 2007; 32:816-823

Comparison to Alternative Treatment

SR (looked at same 4 RCTs as Mirza & Deyo)

- For non-radicular low back pain with common degenerative changes -
 - fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function
 - but slightly to moderately superior to standard (non-intensive) nonsurgical therapy
 - less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion.

Chou R, Baisden J, Chengre BJ, Bessink DK, Shaffer WO, Lamer JD "Surgery for Low Back Pain: A Review of the Evidence for an American Pain Society Clinical Practice Guidelines" Spine 2002;27: 1104-1109

Spinal Fusion in WC Patients

Comparative observational study:

- variety of surgeries performed
 - 78 Anterior lumbar interbody fusion one level
 - 34 Anterior lumbar interbody fusion multiple levels
 - 30 Anterior-posterior 360 one level
 - 39 Anterior-posterior 360 multiple levels
 - 310 Posterior lumbar interbody fusion one level
 - 68 Posterior lumbar interbody fusion multiple levels
 - 26 Posterior un-instrumented one level
 - 5 Posterior un-instrumented multiple levels
 - 47 Posterior with instrumentation one level
 - 88 Posterior with instrumentation multiple levels

Hopman TH, Bamshigh DC, Tidmore J, Sorey P, Trevis R "Long-term Outcomes of Lumbar Fusion Among Workers" Comparative Effects: A Historical Cohort Study" Spine 2011;36:330-331

Spinal Fusion in WC Patients

Comparative observational study:

- 725 WC patients with fusion surgery vs. 725 WC controls (age-, gender- & ICD9- matched)

Spondylolisthesis—acquired/degenerative 738.4
 Radiculitis (leg or lumbar or lumbosacral) 724.4
 Lumbago or sciatica due to displacement of intervertebral disc OR neuritis or radiculitis due to displacement or rupture of lumbar intervertebral disc 722.10
 Lumbar stenosis 724.02
 Spondylolysis lumbar or lumbosacral without myelopathy 721.3
 Degenerative intervertebral disc—Lumbosacral 722.52
 Sciatica 724.3
 Displacement of lumbar intervertebral disc without myelopathy 722.1
 Discogenic syndrome NOS or disc herniation or intervertebral disc NOS (extrusion, prolapse, protrusion, rupture) 722.2

Nayyar TH, Ransdahl DC, Tahaage J, Soreop P, Trevis R. "Long-term Outcomes of Lumbar Fusion Among Workers' Compensation Subjects: A Historical Cohort Study" *Spine* 2011;36:328-331

Spinal Fusion in WC Patients

Comparative observational study:

Main outcome RTW 2 yrs. after surgery vs. RTW 2 yrs. after injury:

- 26% (n=188) of fusion cases had RTW, while 67% (n=483) of non-surgical controls had RTW (P 0.001)

Nayyar TH, Ransdahl DC, Tahaage J, Soreop P, Trevis R. "Long-term Outcomes of Lumbar Fusion Among Workers' Compensation Subjects: A Historical Cohort Study" *Spine* 2011;36:328-331

Spinal Fusion in WC Patients

Comparative observational study:

Other outcomes in fusion patients-

- 36% (n = 264) had complications.
- daily opioid use increased 41% after surgery
- 76% (n = 550) had continuing opioid use after surgery
- 27% (n =194) had a subsequent surgery

Nayyar TH, Ransdahl DC, Tahaage J, Soreop P, Trevis R. "Long-term Outcomes of Lumbar Fusion Among Workers' Compensation Subjects: A Historical Cohort Study" *Spine* 2011;36:328-331

SPINAL FUSION

Effectiveness

American Pain Society Guideline

Recommendation 4

In patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision-making regarding surgery for nonspecific low back pain include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus non-interdisciplinary nonsurgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome (defined as minimum or no pain, discontinuation of or occasional pain medication use, and return of high-level function).

Chou R, Looney JD, Owens DK, Rosenblatt RW, Adler SI, Babin JA, Chagnac EI, Oatis M, Murphy DH, Ransick DJ, Sacco SP, Starlin WJ, Wall E. "Interventions for Chronic Low Back Pain: A Systematic Review of the Literature and an Evidence-Based Clinical Practice Guideline From the American Pain Society" *Spine* 2009;34:1066-1077

Guideline Comparison

Guideline	Recommendation	Strength of Recommendation	Quality of Evidence	Notes
American Pain Society	Discuss risks and benefits of surgery as an option	Weak	Moderate	Based on observational data and expert opinion
Other Guidelines	Various surgical and non-surgical options	Varies	Varies	Includes more detailed clinical criteria