

P&S Network, Inc.

8484 Wilshire Blvd, Suite 620, Beverly Hills, CA 90211

Ph: (323)556-0555 Fx: (323)556-0556

Notice of Independent Review Decision

DATE OF REVIEW: October 13, 2008

IRO CASE #:

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by an orthopedic surgeon, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Two day inpatient stay and L3-L4 decompression, L3-L4 posterior lumbar interbody fusion with cages, posterolateral fusion with plates and screw fixation

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overtaken (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o September 4, 2008 utilization review letter from
- o September 2, 2008 peer review report from
- o September 11, 2008 peer review report from
- o September 11, 2008 peer review letter from
- o September 25, 2008 peer review report from
- o October 1, 2008 peer review letter from
- o June 2, 2008 through September 15 2000 and records from
- o December 8, 2004 and December 12, 2005 operative reports from
- o July 11, 2008 lumbar spine MRI report interpreted by
- o July 23, 2008 through August 13, 2008 medical records from

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records, the patient sustained an industrial injury on xx/xx/xx involving the lumbar spine. The above captioned request was reviewed on September 2, 2008 and a non-certification was rendered. The report notes that the patient has undergone several back surgeries with the first in 2003 consisting of an L4-5 bilateral laminectomy and bilateral posterolateral fusion at L4-5. In December 2004, he underwent revision lumbar laminectomy bilaterally with decompression of the L5 nerve root, arthrodesis interbody/lumbar, instrumentation cages, screws and rods L4-5. On December 2005, he underwent L4-5 exploration and bilateral intertransverse process arthrodesis. Several epidural steroid injections were provided in 2005 as well.

Lumbar spine x-rays were performed on June 25, 2008 according to the September 2, 2008 peer review report. The x-rays reportedly demonstrated changes of anterior interbody fusion L4-5 with interbody graft. He appears to be status post L5 and L4 laminectomy. There is mild disc space narrowing at L3-4 with a significant change in distal angulation from extension to flexion. Initially, there is a slight retrolisthesis of L3 on L4 and extension which reduces in flexion. No compression fractures. No evidence for pars defect. The impression was status post decompression and fusion L4-5 with evidence for early diskal

degeneration and degenerative facet arthropathy at L3-4 resulting in a slight degenerative instability at L3-4.

The patient underwent a lumbar spine MRI on July 11, 2008 with an impression of follows: Status post decompression and fusion L4-5 with mature posterolateral and anterior interbody fusion. Spinal canal and neural foramina are patent. Degenerative disc changes at L3-4 with circumferential disc bulging as well as moderate degenerative facet arthropathy resulting in mild spinal canal stenosis, moderate right and mild left-sided foraminal stenosis. Mild disc bulging T12-L1 without spinal canal or foraminal stenosis.

The first peer review physician stated in the September 2, 2008 report that this gentleman has documented lumbar segmental instability at L3-4 above his previous fusion at L4-5. He has motion on lateral flexion/extension x-rays and a moderate amount of stenosis at this level. He is having both significant back pain and bilateral leg pain. The report quotes the ODG guidelines criteria for proceeding with lumbar fusion. The report states that the source of the claimant's pain has not been clearly elucidated. The nicotine status of the claimant is not known. The guidelines were quoted as stating that extreme caution must be employed with revision surgery for purposes of pain relief as there is less than 50% success rate reported in the medical literature. As this would be at least the fourth spinal procedure, the success rate after multiple procedures is quite low. In addition, the peer review physician pointed out that the patient has ongoing depression and anxiety and a psychological evaluation is required by the ODG guidelines.

The case was reviewed again on September 25, 2008 and another non-certification was determined. The peer review physician pointed out that there had not been a psychological evaluation to ensure that the claimant is a good candidate for the fifth lumbar surgery. The report refers to an August 22, 2008 office note which states that the patient has instability with 17° of motion above the fusion. The report states that the claimant has primarily axial low back pain. The indication of axial back pain has demonstrated poor results for fusion surgery in the peer-reviewed literature according to the physician. The patient has failed epidural steroid injections, medications, and trigger injections. Straight leg raise was positive on August 13, 2008 with intact strength and sensation. The request for the fifth spinal surgery was deemed not medically necessary.

In reviewing the medical records, the June 2, 2008 report states that x-rays of the lumbar spine, including lateral flexion/extension, reveal an impressive new finding with significant motion above the fusion at L3-4. This measures 17°. There is about 2 mm of anterior movement. An August 22, 2008 chart note states that an injection did not help. The patient is having both significant back pain and bilateral leg pain. Surgical treatment was recommended. A September 10, 2008 chart note states that the peer review physician indicated that he was declining the surgery because the patient's nicotine and psychiatric issues have not been resolved. The patient's chart was reviewed and the peer review physician was reportedly called back to inform him that the patient is a nonsmoker and has been under treatment with antidepressant medication for some time. The records clearly reflect that he is quite stable. The peer review physician then informed him that he was still denying the surgery because it was at least the patient's fourth surgery, and he did not feel the surgery would help the patient. A July 23, 2008 report confirms that the patient's review of systems is positive for anxiety, depression, feelings of stress, and a sleep disturbance.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

I would recommend proceeding with the requested surgery. The records clearly indicate transitional stenosis and instability. This will not respond well to non-operative treatment. Smoking is an issue, but that alone should not disallow the surgery. All chronic pain patients have some psychiatric issues as well. A psychological evaluation would be beneficial, but should not be a reason to deny the surgery. Therefore, my determination is to overturn the previous non-certifications of a two day inpatient stay and L3-L4 decompression, L3-L4 posterior lumbar interbody fusion with cages, posterolateral fusion with plates and screw fixation.

The IRO's decision is consistent with the following guidelines:

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

____ ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGBASE

____ AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES

____ DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES

____ EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN Page 5 of 7

____ INTERQUAL CRITERIA

____ MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

____ MERCY CENTER CONSENSUS CONFERENCE GUIDELINES

_____MILLIMAN CARE GUIDELINES

__x__ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

_____PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR

_____TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

_____TEXAS TACADA GUIDELINES

_____TMF SCREENING CRITERIA MANUAL

_____PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE
(PROVIDE A DESCRIPTION)

_____OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

According to the Official Disability Guidelines (2008): Low Back Chapter
Fusion (spinal):

Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "Patient Selection Criteria for Lumbar Spinal Fusion," after 6 months of conservative care. For workers' comp populations, see also the heading, "Lumbar fusion in workers' comp patients." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides (Andersson, 2000)] For complete references, see separate document with all studies focusing on Fusion (spinal). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. (Gibson-Cochrane, 2000) (Savolainen, 1998) (W etzel, 2001) (Molinari, 2001) (Bigos, 1999) (Washington, 1995) (DeBarard-Spine, 2001) (Fritzell-Spine, 2001) (Fritzell-Spine, 2002) (Deyo-NEJM, 2004) (Gibson-Cochrane/Spine, 2005) (Soegaard, 2005) (Glassman, 2006) (Atlas, 2006) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the "carefully selected patient." (Resnick, 2005) (Fritzell, 2004) A recently published well respected international guideline, the "European Guidelines," concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments - including multidisciplinary approaches with combined programs of cognitive intervention and exercises - have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. (Airaksinen, 2006) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. (Ivar Brox-Spine, 2003) (Keller-Spine, 2004) (Fairbank-BMJ, 2005) (Brox, 2006) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. (Bagnall-Cochrane, 2004) (Siebenga, 2006) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. (Wickizer, 2004) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. (Weiner-Spine, 2004) (Shah-Spine, 2005) (Abelson, 2006) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. (Deyo-Spine, 2005) (Weinstein, 2006) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. (CMS, 2006) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. (Burnett, 2006) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. (Hallett, 2007) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. (Martin, 2008) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom

surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 2008) Lumbar spinal fusion surgeries use bone grafts, and are sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae. The therapeutic objective of spinal fusion surgery for patients with low back problems is to prevent any movement in the intervertebral spaces between the fused vertebrae, thereby reducing pain and any neurological deficits. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Lumbar fusion in workers' comp patients: In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. Until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, and this treatment for this condition remains "under study." It appears that workers' compensation populations require particular scrutiny when being considered for fusion for chronic low back pain, as there is evidence of poorer outcomes in subgroups of patients who were receiving compensation or involved in litigation. (Fritzell-Spine, 2001) (Harris-JAMA, 2005) (Maghouth-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 2006) Presurgical biopsychosocial variables predict patient outcomes from lumbar fusion, which may help improve patient selection. Workers' compensation status, smoking, depression, and litigation were the most consistent presurgical predictors of poorer patient outcomes. Other predictors of poor results were number of prior low back operations, low household income, and older age. (DeBerard-Spine, 2001) (DeBerard, 2003) (Deyo, 2005) (LaCaille, 2005) (Trief-Spine, 2006) Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. (LaCaille, 2007) A recent study of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007)

Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. (Eckman, 2005) This study found only a 27% success from spinal fusion in patients with low back pain and a positive single-level low-pressure provocative discogram, versus a 72% success in patients having a well-accepted single-level lumbar pathology of unstable spondylolisthesis. (Carragee, 2006) Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. (Fernandez-Fairen, 2007) Patients with degenerative spondylolisthesis and spinal stenosis who undergo standard decompressive laminectomy (with or without fusion) showed substantially greater improvement in pain and function during a period of 2 years than patients treated nonsurgically, according to the recent results from the Spine Patient Outcomes Research Trial (SPORT). (Weinstein-spondylolisthesis, 2007) (Deyo-NEJM, 2007) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. (Martin, 2007) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration, concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. (Mirza, 2007)

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 2007)

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include: (1) Neural Arch Defect - Spondylytic spondylolisthesis, congenital neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical disectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). (Andersson, 2000)] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two disectomies on the same disc, fusion may be an option at the time of the third disectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Disectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) Psychosocial screen with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. (Colorado, 2001) (BlueCross BlueShield, 2002)