

# P&S Network, Inc.

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

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

**DATE OF REVIEW:** September 23, 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**

Posterior interbody fusion L4-5 with a three day inpatient stay

## **REVIEW OUTCOME**

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

Upheld (Agree)

## **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 May 30, 2008 through June 11, 2008 physical therapy records from
- o June 30 2000 and a lumbar MRI with flexion and extension report by, M.D.
- o June 16, 2008 through August 22, 2008 medical records from Orthopedics, D.O.
- o July 22, 2008 utilization review report by, M.D.
- o August 15, 2008 utilization review report by, M.D.
- o August 22, 2008 IRO request letter from Orthopedics, D.O.

## **PATIENT CLINICAL HISTORY [SUMMARY]:**

According to the medical records, the patient sustained an industrial injury on xx/xx/xx involving the lumbar spine following a slip and fall accident. A June 16, 2008 initial evaluation report states that the patient is a xx year-old female who describes primarily low back pain with left leg lateral thigh pain and left knee pain. She describes numbness and tingling into the left leg. She has had some therapy and it is not certain if it has helped much. She rates her pain as a 10 out of 10 at its worst, however, the patient continues to work. She had duties of cleaning rooms, but now works in the laundry; a position that reportedly entails quite a bit of lifting. She works in services for a local hotel. Relevant examination findings included 3+/4 left quadriceps, hamstrings, and plantar flexion strength; decreased sensation of the left calf and first and fifth toes of her foot on the left; 3+ patellar reflexes and 1+ Achilles reflexes bilaterally; diminished range of motion; and negative straight leg raise bilaterally.

The patient underwent x-rays including flexion and extension views. These revealed mild spondylosis of the L5-S1 disc level. There is also a spondylolisthesis of grade 1 at L4-5 without significant abnormal motion on flexion/extension views. She has a normal lumbar lordosis. Continuation of physical therapy and medications was recommended.

The records include a June 30, 2008 lumbar spine with flexion and extension MRI report. The impression is as follows: T12-L1 2 mm central disc protrusion with no canal stenosis. L1-2 no disc herniation or canal stenosis. L2-3, L3-4 both levels demonstrate a broad 1 mm disc bulge with no canal stenosis. L4-5 grade 1 anterolisthesis contributing to moderate multifactorial central canal

stenosis. The listhesis measures approximately 8 mm in neutral positioning and decreases to 5-6 mm in both flexion and extension. Mild neural foraminal narrowing occurs with extension. L5-S1 broad 2 mm osteophyte disc protrusion complex with no canal stenosis. A zone of hyperintensity on T2 is present along the annular margin suggesting that the disc is acutely irritated and edematous.

The request for posterior interbody fusion at L4-5 was reviewed on July 22, 2008 and was deemed non-certified. The report notes that the claimant complains of low back pain after a slip and fall injury. No past surgical history was documented. A discussion was reportedly held between the physician reviewer and the physician assistant as the physician was not available. The physician assistant confirmed that the claimant is only two months since the date of injury. Only lower levels of care including therapy and medications have been performed. The patient had not received any injections. The lower levels of care had not been exhausted according to the peer review report. The physician reviewer stated that the ODG recommends six months of nonoperative treatment.

The case was again reviewed on August 15, 2008 and another non-certification was provided. This report states that the flexion/extension study does not meet the criteria for spinal instability and the AMA guides which require movement of more than 4.5 mm. The records do not reflect that lower levels of care have been exhausted according to the physician reviewer. The report states that it is apparent that the claimant's spine pathology is not limited to two levels.

A request for an IRO was submitted in a letter dated August 22, 2008. The physician stated that the decision to deny the treatment is not based upon the Official Disability Guidelines. The letter states that the patient was initially seen on June 16, 2008 with complaints of low back pain, bilateral lower extremity pain, and numbness in the left leg. She also exhibited decreased muscle strength in her left quad and hamstring, along with decreased strength into left plantar flexion. Her sensation was decreased in the left calf and in the left first and fifth toes. She stated that she had attended physical therapy and it had not helped. An MRI was ordered and was significant for grade 1 anterolisthesis with moderate central canal stenosis. The listhesis measures approximately 8 mm in neutral and decreases to 5-6 mm in both flexion and extension. Mild neural foraminal narrowing occurs with extension. There are some issues at some other levels as well, but are not clinical at this time. Physical therapy was again ordered, but the patient once again reported increase in pain and rated it at 10/10. Medications were also dispensed that include Ultram, flexeril, and naproxen. None of these medications were beneficial. The patient is a nonsmoker and denies alcohol use. The letter addresses excerpts from the Official Disability Guidelines that were cited in the peer review reports. To address the line in the ODG that states that there is insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis, the physician noted that the patient has an acute injury and she exhibits spondylolisthesis documented by MRI. The ODG recommends fusion as a treatment option for spondylolisthesis. The physician also stated that he does not believe that the spinal levels where a 1 mm disc protrusion exist without clinical correlation represents pathology as described by the reviewer when he states that there is more than one level of pathology and so fusion should be excluded. The physician express willingness to pursue a psychosocial assessment if necessary.

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

The Official Disability Guidelines clearly state that at least six months of conservative management should be completed prior to consideration for fusion unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction. The records reflect that flexion-extension x-rays revealed a grade 1 spondylolisthesis without movement upon the dynamic studies. However, the patient also underwent a flexion-extension MRI which revealed an 8 mm anterolisthesis which decreases to 5-6 mm in both flexion and extension. These are contradictory results. At any rate, a grade 1 spondylolisthesis would not qualify as severe structural instability.

It should also be pointed out that there is a discrepancy between the patient's reported pain level of 10/10 in the initial evaluation and the fact that she continued to work in a position in the laundry room which reportedly entailed a fair amount of lifting. In addition, the records fail to document demonstration of a progressive neurologic dysfunction. However, the patient does demonstrate neurologic deficits and positive imaging findings. This would potentially qualify the patient for surgical intervention had she failed six months of conservative management. The Official Disability Guidelines also recommend a psychosocial screen prior to lumbar fusion. As noted above, the physician has expressed willingness to proceed with such a screen if necessary. Given that the patient has not completed six months of conservative management and the psychosocial screen, my determination is to uphold the previous decisions to non-certify the request for posterior interbody fusion L4-5 with a three day inpatient stay.

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
- \_\_\_\_ 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

Official Disability Guidelines (2008): Lumbar 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) (Maghout-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 - Spondylolytic 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 discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

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)