

C-IRO, Inc.

An Independent Review Organization
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Austin, TX 78726

Notice of Independent Review Decision

DATE OF REVIEW:

August 20, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

360 degree fusion anterior posterior lumbar fusion L4-5, L5-S1

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

Board Certified Orthopedic Surgeon

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Lumbar spine MRI, 05/04/06
Office notes, Dr., 08/31/06, 09/27/06, 10/25/06, 11/08/06, 12/13/06, 01/29/07, 02/26/07,
03/31/07, 03/10/07, 04/26/07
Operative report, 09/19/07
Discharge summary, 09/20/07
Lumbar MRI with and without contrast, 02/01/07
Discogram, 04/18/07
Office note, Dr., 05/31/07
Case notes

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male injured on xx/xx/xx when he bent over and felt pain in the low back. A 05/04/06 MRI of the lumbar spine showed L1-2 and 2-3 were normal. There was an L3-4 bulge. At L4-5 there was a moderate herniation centrally and to the right with a possible free fragment with compression on the nerve root and thecal sac and with moderate spinal and foraminal

stenosis due to facet degeneration and disc dessication. At L5-S1 there was a protrusion with no compression and early spinal stenosis due to facet hypertrophy and disc dessication. On 9/19/07 the claimant underwent an L4 laminectomy with L4-5 partial discectomy. He did well after surgery and was started in therapy.

By 01/29/07 Dr. reported the claimant had back and left leg pain, but no weakness or numbness. The neurological examination was intact. On 02/01/07 a lumbar MRI with and without contrast showed narrowing at L4-5 with previous surgery noted. There was mild annular bulging at L5-S1 with a central annular tear but no stenosis and no facet changes. The claimant then had a discogram on 04/18/07 that documented L3-4 was normal. At L4-5 there was strong concordant pain at 8/10 and at L5-S1 there was 10/10 concordant pain. Dr. saw the claimant on follow up and on examination there was 5/5 strength, normal sensation and a negative straight leg raise. An EMG was done on 05/31/07 that was reported as suggesting radiculopathy. Fusion at L4-5 and L5-S1 has been recommended and denied. Resolution has been requested.

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

A lumbar 360 degree fusion with a three day length of stay does not appear to be medically necessary or reasonable. This is based upon the medical records available to the reviewer in this xx year-old claimant with axial pain without any instability. He underwent an L4 laminectomy and L4-5 partial discectomy on 9/19/07. A post operative MRI on 02/01/07 demonstrated narrowing of the L4-5 disc space and mild annular bulging at L5-S1. Per report of Dr., an MRI shows an L5-S1 compression fracture. This however was not noted in the official report. Discogram demonstrates L3-4 to be normal, L4-5, 8/10 strong concordant pain and 10/10 concordant pain at L5-S1. This claimant is documented to be neurologically intact and EMG shows some suggestion of radiculopathy per physiatrist Dr. on 05/31/07. There is no psychosocial screen noted to sift through any confounding issues. In addition, it is unclear what levels are being proposed and whether or not all the pain generators have been appropriately identified. As well, it is not evident that the claimant has exhausted an appropriate course of conservative measures. As such, the Reviewer would not recommend revision spine surgery based upon the medical information for this review.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, Low Back-Fusion Not recommended for patients who have less than six months of failed conservative care unless there is 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 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 recommended [conservative therapy](#). 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, but studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. ([Gibson-Cochrane, 2000](#)) ([Savolainen, 1998](#)) ([Wetzel, 2001](#)) ([Molinari, 2001](#)) ([Bigos, 1999](#)) ([Washington, 1995](#)) ([DeBarard-Spine, 2001](#)) ([Fritzell-Spine, 2001](#)) ([Fritzell-Spine, 2002](#)) ([Deyo-NEJM, 2004](#)) ([Gibson-Cochrane/Spine, 2005](#)) ([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](#)) Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. ([Eckman, 2005](#)) 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. ([Devo-Spine, 2005](#)) ([Weinstein, 2006](#)) Outcomes from demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. ([van Tulder, 2006](#)) ([Maghout, 2006](#)) A recent 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](#)) 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](#)) 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](#)) ([Devo-NEJM, 2007](#)) 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](#)) 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.

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](#)) ([Atlas, 2006](#)) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. ([Texas, 2001](#)) ([NCCL, 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. Also predictors 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](#))

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 unilateral neural arch hypoplasia. (2) Segmental Instability - 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. (3) Primary Mechanical Back Pain/Functional Spinal Unit Failure, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability, with and without neurogenic compromise. 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. (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.

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion 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-ray demonstrating spinal instability and/or MRI, Mylogram or CT discography 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

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 KNOWLEDGEBASE
- 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
- 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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)