

Independent Resolutions Inc.

An Independent Review Organization

835 E. Lamar Blvd. #394

Arlington, TX 76011

Phone: 817-274-0868

Fax: 817-549-0311

IRO REVIEWER REPORT TEMPLATE -WC

DATE OF REVIEW: JULY 16, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Bilateral laminectomy/decompression L3-4, right sides laminectomy L2-3, L5-S1, posterior spinal fusion L3-S1 with pedicle screws, removal of facet screws L4-5, TLIF Aesculap device L5-S1 and a two day inpatient stay.

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Lumbar spine MRI, 03/31/92 and 04/01/92
Letter, Dr. 04/08/02, 11/16/92 and 04/22/93
Operative report, Dr. 06/02/92 and 11/16/92
Note, 07/27/00
Operative report, 08/23/00, 01/06/03

Office notes, Dr. 03/27/07 and 05/08/07
Office notes, Dr. 04/17/07
Lumbar CT myelogram, 05/02/07
Office note, Dr. 06/07/07
Peer review, Dr. 06/19/07
Denial Letters from URA

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male warehouse helper who underwent a L4-S1 360 fusion. The records suggest the claimant did relatively well for years and then began developing increasing low back pain. The claimant began treating with Dr. for low back pain with radiation down his anterior thigh but not distally. The claimant noted some paresthesias from the medial aspect of his right thigh to his foot. The claimant had been treated with physical therapy, medications and epidural steroid injections in the past. Exam findings revealed pain with extension, negative straight leg raise and a right sided positive femoral stretch test. There was quadriceps weakness and diminished sensation to the medial calf and foot. The right knee jerk was absent. Lumbar radiographs that day including flexion and extension views showed retrolisthesis of L5 on S1 and early canal narrowing of the disc space and deterioration of the facet joints at L5-S1 consistent with adjacent segment deterioration. There was evidence of preservation of disc height but some anterior bridging syndesmophyte formation at L3-4 and L4-5 levels. The diagnosis was right lumbar radiculopathy at L4, L4 motor and sensory impairment, and adjacent deterioration at L5-S1.

Dr. performed electromyography on 04/17/07 which showed chronic L4 radiculopathy and chronic bilateral L5-S1 radiculitis, slightly worse on the left. Dr. saw the claimant on 05/08/07. Dr. felt that the lumbar CT myelography showed high a grade block at L3-4, disc space narrowing and retrolisthesis of L3 on L4 with a superimposed 9 millimeter broad based right sided posterolateral protrusion markedly narrowing the right foramen, effacement and displacement of the right L3 nerve root, and below the fusion at L5-S1, there was evidence of a right sided disc herniation with kissing spinous processes and marked lateral stenosis. Dr. noted a right sided 8 millimeter broad based protrusion. Dr.'s impression was severe spinal stenosis at L3-4 with disc herniations at L2-3, L3-4 and L5-S1 with evidence of deterioration of the adjacent motion segments with respect to the fused area of L4-5. Dr. recommended a wide decompression at L3-4 level bilaterally with extension and fusion above the fusion at L3-4 and L5-S1 levels with removal of disc herniations. At L2-3, a right sided discectomy would be performed.

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

The requested bilateral laminectomy, decompression at L3-4, right sided laminectomy L2-3, L5-S1, posterior spinal fusion from L3 to S1 with pedicle screws, removal of facet screws at L4-5, trans lumbar interbody fusion and two day inpatient stay does not appear to be medically necessary nor reasonable in this year-old male who is status post in 1992 a fusion at L4-5 for a herniated nucleus pulposus. He did well for a period of time and returned back to functional work. He then again developed pain in early 2004 and had been seen by Dr. Symptomatology is now reportedly related to the adjacent levels of L3-4 and L5-1. There was retrolisthesis at L3-4 with some possible instability noted and radiculopathy. Decompression and fusion at this level would

appear to be reasonable at the L5-S1, which per EMG and nerve conduction demonstrates chronic radiculitis, fusion does not appear to be indicated. There is no sign of instability at this level and nerve root sleeves fill normally and there is no nerve root displacement. The request for Bilateral laminectomy/decompression L3-4, right sides laminectomy L2-3, L5-S1, posterior spinal fusion L3-S1, with pedicle screws, removal of facet screws L4-5, TLIF Aesculap device L5-S1 and a two day inpatient stay does not appear to be reasonable based on the levels mentioned, symptomatology and findings.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, Low Back, Lumbar and Thoracic

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. 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." 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. Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. 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. For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis may be candidates for fusion. 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 demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout, 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) 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) (Deyo-NEJM, 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.

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 discectomy. (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, Myelogram 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. (Colorado, 2001) (BlueCross BlueShield, 2002)

Milliman Guidelines, Inpatient Surgical 11th Edition

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)