

P-IRO Inc.

An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW:

AUGUST 21, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal Surgery (LOS)

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 x-ray, 10/13/06
Thoracic and cervical spine x-ray report, 10/13/06
Office notes, 11/01/06, 11/03/06, 11/08/06, 11/13/06, 11/17/06, 12/13/06, 12/20/06, 02/12/07, 02/19/07 and 03/05/07
Lumbar spine MRI, 11/16/06
Thoracic spine MRI report, 11/16/06
Office note, Dr. 12/06/06
Office note, RN, ANP-C for Dr. 01/04/07
Lumbar spine epidural steroid injection, 01/22/07
Office note, Dr. 02/15/07
Office notes, Dr. 04/09/07, 06/21/07, 8/16/07
Review of medical records, Dr. 04/12/07
Office note, Dr. 05/01/07
Discogram, 05/10/07
Behavioral med screening, 06/06/07

Denial 06/15/07
Review, Dr. 07/03/07
Office note, PA for Dr. 07/13/07

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx year old male who has been treating for greater than 11 months for primarily low back pain. The MRI of the lumbar spine on 11/16/06 revealed at the L5-S1 level, an approximately 4 millimeter central to left parasagittal soft tissue disc protrusion extrusion that narrowed the prethecal epidural space at the level of the S1 nerve root. At the L4-5 level, a 1-2 millimeter annular bulge was seen to touch and slightly efface the thecal sac. The claimant has been treating with Dr. for physical therapy, medications, light duty and epidural steroid injections without benefit. On 04/09/07, Dr. noted that there was no evidence of instability on flexion extension views. A 05/10/07 three level discogram revealed concordant pain at L5-S1 with L3-4 and L4-5 as negative control levels. According to the office note on 07/13/07, the claimant has been evaluated by psychology and has reduced his consumption of smoking. An anterior lumbar interbody fusion at L5-S1 has been requested.

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

The claimant is a xx year-old gentleman who injured his back in xx/xx/xx. Since that time he has had back and radicular leg complaints. He underwent an 11/16/06 MRI of the lumbar spine that showed an L5-S1 disc extrusion. He has been treated conservatively with activity modification, home exercises, epidural steroid injections and medication. He has had flexion/extension x-rays that do not show instability and has had a discogram that shows pain at L5-S1 with other negative levels. An L5-S1 fusion has been requested.

It is not clear to the Reviewer as to the medical indication for the requested anterior lumbar interbody fusion at L5-S1. In light of the fact that it appears to the Reviewer this claimant has a herniated disc giving him back and radicular leg complaints, and no evidence of structural instability, there is no need for a fusion. After reviewing the medical record the Reviewer believes that his complaints of pain on discogram could be consistent with a disc herniation and not with a need for fusion. There is no documentation of structural instability, fracture, infection, or other significant abnormality. It is not clear to the Reviewer why a fusion has been requested as a primary operation rather than a discectomy.

Therefore, based on this medical record the Reviewer does not see the medical indication for the requested fusion.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates, low back

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.” 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. 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. The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. 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. Outcomes from demanding surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. 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. 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. 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. Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. 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). 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. 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. Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. 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. Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion.

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 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) 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)