

# IRO Express Inc.

An Independent Review Organization

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**DATE OF REVIEW:** July 25, 2007

**IRO CASE #:**

## **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

L5 partial corpectomy, radical anterior L5 discectomy, anterior lumbar interbody fusion at L5, internal fixation at L5 with PEEK interbody fusion cage, iliac crest marrow aspirate, and bone graft substitutes/allograft with anterior lumbar plating

## **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**

Physical therapy initial evaluation, 03/01/06

Physical therapy daily notes, 03/02/06 to 03/30/06 and 04/19/06

Lumbar spine MRI, 03/27/07

Pain Management notes, 04/19/06, 05/12/06, 05/31/06, 07/10/06, 07/31/06, 08/21/06, 10/09/06, 11/08/06, 12/08/06, 02/23/07, 03/23/07, 04/27/07 and 05/30/07

Procedure, 05/16/06, 08/10/06

Independent Medical Evaluation, Dr. 10/17/06

Functional capacity evaluation, 01/19/06

Functional capacity evaluation report, 10/20/06

Rebuttal by Dr. 11/30/06

Lumbar spine CT scan, 02/01/07

Lumbar discogram, 02/01/07

HEALTH AND WC NETWORK CERTIFICATION & QA 9/27/2007

IRO Decision/Report Template- WC

Office notes, Dr. 05/11/07, 05/24/07 and 06/07/07  
Review determination, 05/18/07  
Review determination, 06/06/07  
Letter from Dr. 07/03/07  
IRO summary noted, 07/12/07

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a female stocker and loader who complained of low back pain radiating to the lower extremities with numbness and tingling in the toes after working a night shift. An MRI of the lumbar spine on 03/27/06 showed degenerative changes, with a small annular tear and minimal disc bulge at L5-S1 and mild facet joint osteoarthritic changes causing mild bilateral neural foraminal narrowing at L4-5. The claimant treated with physical therapy, multiple medications, trigger point injections and two transforaminal epidural steroid injections without significant relief. A Pain Management office note on 10/09/06 indicated that an NCV study showed a moderate left L5 radiculopathy and examination found decreased right extensor hallucis longus strength. An Independent Medical Evaluation by Dr. on 10/17/06 found no objective physical findings to correlate with subjective complaints, marked signs of symptom magnification, poor effort and secondary gain factors, and ability to work at a sedentary level. Additionally, Dr. interpreted the MRI as showing no annular tear or impact on the spinal cord or neural structures. The Pain Management physician disagreed with Dr.'s report and restricted the claimant from bending, twisting, pushing or pulling as well as restriction from lifting greater than 10 pounds.

A three level discogram on 02/01/07 found concordant pain at L5-S1 and non-painful levels at L3-4 and L4-5, and a CT scan also on 02/01/07 showed a large central disc herniation at L5-S1 with annular tear and contrast leak with mild compression of the right traversing S1 nerve root, in addition to mild disc bulges at L3-4 and L4-5. The claimant was examined by Dr. on 05/11/07 for complaints of continued low back pain greater than right lower extremity pain. No focal motor or sensory deficits were noted on examination. Dr.'s assessment was L5 large central disc herniation with annular tear, lumbar discogenic pain syndrome and right lower extremity sciatica. He recommended surgical intervention in the form of L5 partial corpectomy, radical anterior L5 discectomy, anterior lumbar interbody fusion at L5, internal fixation at L5 with PEEK interbody fusion cage, iliac crest marrow aspirate, and bone graft substitutes/allograft with anterior lumbar plating.

On 05/18/07 the surgical request was non-certified by preventive medicine physician Dr. as spinal instability had not been established, there was no history of prior decompression, the request appeared predicated on the discogram results, and the IME findings of significant symptom magnification. Dr. requested an appeal, citing the discrepancy between the Independent Medical Evaluation findings and his findings on physical examination. On 06/06/07 the surgical request was again non-certified by orthopedic surgeon Dr. based on discography being a poor indicator of fusion outcome surgery as well as the fusion being done for internal disc derangement in the absence of documented instability. Dr. responded to the non-authorization determination on 06/07/07, noting that the claimant, in his opinion, met the Official Disability Guidelines #3 requirement under spinal fusion, as the claimant had "primary mechanical back pain/functional spinal unit failure including 1 or 2 level segmental failure with progressive degenerative changes, loss of height, disc loading capability with and without neurological compromise".

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

The requested lumbar fusion for possible discogenic pain does not appear to be consistent with Official Disability Guidelines. The claimant was documented by Dr. on 10/17/06 to have evidence of symptom magnification and inappropriate pain behavior. The MRI was interpreted to show hydration of the disc and Dr.'s review showed no true annulus tear. The claimant still has not apparently received psychosocial screening. Though Dr. states that the claimant had no Waddell signs upon his evaluation, the medical records would indicate some concern for this and a psychosocial screen would therefore be appropriate. The claimant is noted, even by Dr. to have situational depression and certainly this would also seem to warrant a psychosocial evaluation. Though the claimant meets many of the Official Disability Guidelines, the Reviewer does not believe that they have been completely fulfilled and is, therefore, unable to justify the request for the fusion based on the information provided.

### Official Disability Guidelines Treatment in Worker's 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." 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. 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. Cryosurgical 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. 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. 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.

**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)**