

DATE OF REVIEW: 9/13/07**IRO CASE #:****DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Transforaminal lumbar interbody fusion L4-L5, L5-S1.

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

This case was reviewed by a board certified orthopedic surgeon on the MAXIMUS external review panel who is familiar with the condition and treatment options at issue in this appeal.

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)

<i>Primary Dx Code</i>	<i>HCPCS/ NDC</i>	<i>Units</i>	<i>Begin/End Date</i>	<i>Type Review</i>	<i>Amt Billed</i>	<i>Date of Injury</i>	<i>DWC Claim #</i>	<i>Uphold / Overturned</i>
724.4	63043		7/5/07-9/28/07	Prospective				Uphold
722.83	63043		7/5/07-9/28/07	Prospective				Uphold

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Request for Independent Review by an Independent Review Organization forms – 8/30/07.
2. Determination Notices – 7/11/07 and 7/20/07.
3. Records and Correspondence from Hospital– 1/4/07-4/11/07.
4. Records and Correspondence from DO – 4/20/06-12/14/06.
5. Records and Correspondence from Medical Center – 3/21/07-6/29/07.
6. Records and Correspondence from Medical Center – 7/17/06-9/7/06.
7. Records and Correspondence from Hospital– 4/18/07.

8. Records and Correspondence from Diagnostic Center – 8/15/06.
9. Records and Correspondence– 4/12/06.

PATIENT CLINICAL HISTORY:

This case concerns an adult male who sustained a work related injury. Records indicate the member sustained injury to his back. The circumstances of the injury are not detailed in the available records. Diagnoses have included post laminectomy syndrome, degenerative joint and disc disease, thoracic and lumbosacral neuritis or radiculitis. Evaluation and treatment for this injury has included surgery, physical therapy, MRIs, and medications.

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

The Official Disability Guidelines Treatment in Workers' Compensation 2007 Updates for low back indicate: 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 six 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' compensation 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 - 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) 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.

The claimant is a male who has a history of back pain. He underwent two previous lumbar operations on 7/17/06 for an L4-L5 and L5-S1 disectomy and partial facetectomy as well as a 9/6/06 revision laminectomy, microdisectomy and partial facetectomy L4-L5 and L5-S1. He has continued to have complaints and his diagnostic studies appear to show decreased L4-L5 and L5-S1 disc space height. He has not apparently had documentation in the medical records of an infection, recurrent disc herniation, structural instability with increased angular or listhesis motion on flexion extension, or an abnormal discogram documenting a painful segment. While this person has ongoing complaints of pain, the Official Disability Guideline indications for fusion would be structural instability, infection or need to do a third operative procedure for disc herniation. In light of the fact that this medical records does not seem to indicate any of those diagnoses, there is no medical indication for the requested two-level (L4-L5 and L5-S1) interbody fusion. Therefore, the requested transforaminal lumbar interbody fusion L4-L5, L5-S1 is deemed not medically necessary at this time.

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)