



Notice of Independent Review Decision

DATE OF REVIEW: 3/5/08

IRO CASE #:

NAME:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Determine the appropriateness of the previously denied request for anterior lumbar interbody fusion (ALIF) at L5-S1, with a 3-day inpatient stay.

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

Texas Licensed 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.

The previously denied request for anterior lumbar interbody fusion (ALIF) at L5-S1, with a 3-day inpatient stay.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Confirmation of Receipt of a Request for a Review dated 2/22/08.
- Fax Cover Sheet/Message dated 2/27/08.
- Flexibility Notes (unspecified date).

- Office Visit/Letter dated 2/12/08.
- Pre-Authorization Request dated 1/16/08, 1/3/08, 12/17/07.
- Workmans Compensation Follow-Up dated 1/30/08, 6/28/07, 3/15/07, 2/1/07.
- Electrodiagnostic Studies Report dated 1/22/07.
- Referral Form dated 3/15/07.
- Utilization Review Findings dated 2/14/08, 1/22/08.
- Radiology Report dated 1/8/08.
- Response Letter dated 2/27/08.
- Physical Examination Report/Letter dated 3/26/07.
- History and Physical Examination dated 1/8/08, 1/4/07.
- Re-Evaluation dated 11/27/07.
- Lumbar Spine MRI dated 12/19/07, 11/18/06, 11/11/05.
- Progress Notes dated 2/22/08, 1/14/08, 12/27/07, 12/17/07, 5/11/07, 4/20/07.
- Mental Health Evaluation dated 2/6/08.
- Notice of Assignment of Independent Review Organization dated 2/25/08.
- Notice to CompPartners dated 2/25/08.
- Request for a Review by an Independent Review Organization Form dated 2/15/08.
- Report of Medical Evaluation (unspecified date).

PATIENT CLINICAL HISTORY (SUMMARY):

Age: xx years

Gender: Female

Date of Injury: xx/xx/xx

Mechanism of Injury: Lifting injury.

Diagnosis: Degenerative disk disease of the lumbar spine.

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

This is a xx year old female who reportedly suffered an injury to her back in xx/xx/xx while holding a child. She is now more than three years into conservative care. Records were submitted for the purposes of determining the medical necessity of the proposed anterior lumbar interbody fusion (ALIF) L5-S1. The records document continued pain complaints, not only in the back, but in the neck and midback as recent as a year ago, in January of 2007.

The lumbar spine report on 11/11/05, showed a right paracentral 4 millimeter protrusion at L5-S1. The cervical and thoracic MRI reports were reviewed. The MRI of the lumbar spine report on 11/18/06, showed L5-S1 disc degeneration including a small herniation with a viable annular tear, but without stenosis or evidence of neural impingement. Dr. , evaluated the claimant on 01/04/06 for complaints of neck, mid back and low back pain. The claimant noted right leg pain and a burning sensation to the lumbar spine. The

claimant had been treated with Mobic, Darvocet, and chiropractic treatment. Examination revealed no weakness, some myofascial thoracic pain and restricted range of motion of the lumbar spine. Diagnosis was L5-S1 disc protrusion and facet disease at multiple levels. Dr. recommended epidural steroid injection and medications. The 01/22/07 electromyography report revealed a left L5-S1 radiculopathy.

The claimant began treating with Dr. on 02/01/07 for persistent back, leg and neck pain. The claimant reported that the first injection provided relief. She was working light duty. Examination revealed improvement of range of motion. She had a negative straight leg raise. A second epidural injection was recommended. Dr. performed an impairment evaluation on 03/26/07 and gave the claimant a 15% whole person impairment rating. Dr. saw the claimant on 05/11/07 and on 06/28/07 and felt that the claimant was improving. Dr. referred the claimant to a neurosurgeon on 11/27/07. Dr. saw the claimant on 12/17/07. Dr. impression was discogenic pain with some radiculopathy. Dr. recommended an MRI which was performed on 12/19/07 and showed degenerative disc disease at L5-S1 and a small extrusion posteriorly to the left L5 vertebral body. On 12/2/07, Dr. reviewed the MRI and recommended a discogram. The 01/08/08 lumbar spine X-ray report was negative. The 01/08/08 discogram report was positive at L5-S1. Dr. recommended a L5-S1 lumbar fusion on 01/14/08.

The claimant saw Dr. on 01/30/08. Examination revealed strength was 5/5 and reflexes were 2+. Dr. felt that the claimant's symptoms were worsening. A 02/06/08 mental health evaluation was performed and deemed no contraindications to surgery. Dr. authored a 02/12/08 letter noting that the claimant had mostly low back pain with the 12/19/07 MRI showing discogenic pathology at L5-S1 and a 01/08/08 pathologic response at L5-S1.

This is claimant has had more than three years into conservative care. The records document continued pain complaints, not only in the back, but in the neck and midback as recent as a year ago, in January of 2007. The request is for the medical necessity of the proposed ALIF L5-S1. Electromyograms at the time suggested that the claimant suffered from radiculopathy, although the electromyograms did not completely explain her ongoing complaints of pain in the neck and shoulders. In March of 2007, she was complaining of paresthasias into her hands with pain radiating to the elbows, feet, legs, and into her neck. Her examination revealed a multitude of findings, including weakness in a variety of muscle groups that would not be consistent with her electromyograms. Subsequently, she had continued to complain of ongoing pain and was recommended to undergo lumbar surgery based on concordant discography from January of 2008.

While the discography was clearly concordant and this individual has certainly been through an exhaustive period of conservative care, there are no compelling indications for spinal surgery in this case. There is no evidence of documented spinal instability. There is no evidence of progressive neurologic deficit. Furthermore, although the psychiatric evaluation reports that there are no psychological issues that would preclude her from making a satisfactory recovery; the records in themselves do not explain the plethora of musculoskeletal complaints that would not be well treated by an isolated lumbar fusion at L5-S1. In fact, the focus of the more recent records is solely on the back pain, but it does not address as to whether or not she has had resolution of a variety of other musculoskeletal complaints that may, in fact, overshadow those.

In light of these particular findings, the proposed surgery cannot be recommended as reasonable or medically necessary. These statements are made in consideration of ODG guidelines and other evidence-based literature which describes less than optimal results in individuals with chronic back pain with other confounding complaints.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM – AMERICAN COLLEGE OF OCCUPATIONAL AND 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.

Official Disability Guidelines (ODG), Treatment Index, 6th Edition (web), 2008, Low back—Fusion.

Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated 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 6 months of conservative care. For workers’ comp populations, see also the heading, “Lumbar fusion in workers’ comp patients.” 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 compliance with recommended conservative therapy. [For spinal instability criteria, see AMA Guides (Andersson, 2000)] 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. 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) (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) 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 complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. (van Tulder, 2006) (Maghout-Juratli, 2006) Despite the new technologies, reoperation rates after lumbar fusion have become higher. (Martin, 2007) 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) 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) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. (Derby, 2005) (Derby2, 2005) (Derby, 1999) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. (Martin, 2008) 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) (Maghout-Juratli, 2006) (Atlas, 2006) Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. (Texas, 2001) (NCCI, 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. Other predictors of poor results 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 of 725 workers' comp patients in Ohio who had lumbar fusion found only 6% were able to go back to work a year later, 27% needed another operation, and over 90% were in enough pain that they were still taking narcotics at follow-up. (Nguyen, 2007) Lumbar fusion for spondylolisthesis: Recommended as an option for spondylolisthesis. Patients with increased instability of the spine after surgical decompression at the level of degenerative spondylolisthesis are candidates for fusion. (Eckman, 2005) This 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) 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) For degenerative lumbar spondylolisthesis, spinal fusion may lead to a better clinical outcome than decompression alone. No conclusion about the clinical benefit of instrumenting a spinal fusion can be made, but there is moderate evidence that the use of instrumentation improves the chance of achieving solid fusion. (Martin, 2007) A recent systematic review of randomized trials comparing lumbar fusion surgery to nonsurgical treatment of chronic back pain associated with lumbar disc degeneration concluded that surgery may be more efficacious than unstructured nonsurgical care but may not be more efficacious than structured cognitive-behavior therapy. Methodological limitations of the randomized trials prevented firm conclusions. (Mirza, 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 neural arch hypoplasia. (2) Segmental Instability (objectively demonstrable) - 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. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). (Andersson, 2000) (Luers, 2007)] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental

failure with progressive degenerative changes, loss of height, disc loading capability. 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. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). (Andersson, 2000)] (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. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.) Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should 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-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI 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)

- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR.

- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE AND 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).