



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WC

DATE OF REVIEW: 12-10-10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

TLIF L5, S1, PSF L5-S1, exploration of spinal fusion, removal of hardware, debride pseudoarthrosis and release TLIF, spinal monitoring, and 5 day inpatient stay

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

American Board of Orthopaedic Surgery-Board Certified

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

- 1-9-06 X-rays of the lumbar spine.
- 5-9-06 X-rays of the lumbar spine.
- 5-9-06 CT scan post myelogram.
- 1-26-07 EMG/NCS performed by MD.
- MD., office visits on 6-26-08, 1-15-09, 4-23-09, 9-3-09, 2-11-10, 4-29-10, and 8-26-10.
- 3-5-10 X-rays of the lumbar spine with lateral neural-flexion-extension views.
- 6-29-10 lumbar hardware block bilaterally at L5-S1 performed by, MD.
- 10-11-10 Pre surgical psychological evaluation performed by, LPC.
- 11-2-10, DO., performed a Utilization Review.
- 11-29-10 MD., performed a Utilization Review.

PATIENT CLINICAL HISTORY [SUMMARY]:

1-9-06 X-rays of the lumbar spine shows a successful fusion at L5-S1. No evidence of significant motion on flexion/extension.

5-9-06 X-rays of the lumbar spine showed metal and bony L5-S1 fusion in near anatomic position.

5-9-06 CT scan post myelogram showed at L5-S1 bony fusion and hardware seating are solid and the central dural sac, the root sleeves and the neural foraminal are ample. The right S3 root shows thickening and possible adhesions dorsally at some points along its course.

1-26-07 EMG/NCS performed by MD., showed findings indicative of an old chronic right lower lumbosacral radiculopathy primarily involving the S1, S2 and S3 nerve roots but no evidence of any acute radiculopathic process at the present time.

Follow up with Dr. on 2-10-10 notes the claimant has symptoms of pseudoarthrosis. He has been getting worse. He continues to work.

3-5-10 X-rays of the lumbar spine with lateral neural-flexion-extension views shows metal and bony L5-S1 fusion in anatomic position. There is no excursion at L5-S1 on the flexion/extension views, and the fusion confluent. Otherwise unremarkable.

Follow up with Dr. on 4-29-10 notes the claimant has a solid fusion and possible painful hardware. The evaluator recommended injection hardware. His medications include Hydrocodone, Lyrica and Soma.

On 6-29-10, the claimant underwent a lumbar hardware block bilaterally at L5-S1 performed by MD.

8-26-10 MD., the claimant is a man that has a L5-S1 fusion with instrumentation. He has had provocative injection of hardware. The injections were successful in eliminating the claimant's back pain. He had some paralysis of his legs and numbness from the waist down. He states his pain is now worse than it was prior to the injection. He continues to work a busy job. He uses a stimulator and medications. CT scan showed lucency along the cage suggesting pseudoarthrosis. On exam, the claimant has decreased range of motion. Gait is normal. Motor exam is 5/5. DTR are 3/3 bilateral. Sensation is normal. The evaluator recommended removal of hardware and exploration of the fusion and revise TLIF if pseudo is found. The claimant is continued with medications.

10-11-10 Pre surgical psychological evaluation performed by LPC., notes there are no psychological contraindications for the claimant to undergo the proposed surgical procedure.

On 11-2-10. DO., performed a Utilization Review. The request for transforaminal interbody fusion at L5-S1; posterior spinal fusion at L5-S1; exploration of spinal fusion, removal of hardware, debridement pseudoarthrosis and release transforaminal interbody fusion; spinal monitoring and five days of in-patient stay is not recommended as medically necessary. As stated in the report dated 8-26-10, the patient is status post lumbar fusion with instrumentation and has had provocative injections of hardware. He presented with low back pain. The provider requested surgical intervention as described above. With reference to the records reviewed, there is no objective documentation of the patient's clinical and functional response to an optimized course of conservative treatment that includes Physical Therapy and therapeutic exercises. The clinical findings documented in the report dated 8-26-10 do not indicate progression of neurologic deficits as described in the referenced guidelines. There are no treatment records which show that appropriate modalities were maximized to treat possible pain generators. The official results of recent imaging studies such as the recent CT scan showing the supposed lucency were not provided for review. As such, this request is not certified. Attempts were made to reach the provider but were unsuccessful. Because an adverse determination for surgery has been rendered, an

adverse determination for any associated pre-operative clearance is also rendered.

11-29-10 MD., performed a Utilization Review. The reviewer was not able to speak with Dr.. ODG for patient selection criteria for lumbar spine fusion require objective demonstration of segmental instability at the proposed level of fusion defined as relative angular motion greater than 20 degrees and/or lumbar intersegmental movement of more than 4.5 mm. In the claimant's case, there is no radiographic documentation of abnormal motion or instability at L5-S1. Such a finding would indicate the absence of a pseudoarthrosis. Additionally, the claimant's CT scan revealed a solid fusion posterolaterally as well as at the cages interbody. The evaluator reported that revision surgery for purposes of pain relief must be approached with extreme caution due to less than 50% success rate reported in the medical literature. The evaluator reported that based on the facts, the proposed surgery on appeal, a transforaminal lumbar interbody fusion at L5-S1, pedicle screw fixation L5-S1, exploration of spinal fusion, removal of hardware, debridement of pseudoarthrosis, and release of TLIF, spinal monitoring and a 5 day inpatient length of stay cannot be considered medically appropriate or medically necessary.

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

CAT scan has shown solid posterior-lateral fusion. The lucency noted about the cages is not an indication of instability of the spine.

The proposed surgery has greater risk than benefits to the claimant. Therefore, I do not believe that TLIF L5, S1, PSF L5-S1, exploration of spinal fusion, removal of hardware, debride pseudoarthrosis and release TLIF, spinal monitoring, and 5 day inpatient stay is reasonable or medically indicated.

ODG-TWC, last update 11-12-10 Occupational Disorders of the 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) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. (Chou, 2008) This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. (Hansson, 2008) Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) In a study of 2,378 Washington State workers' compensation claimants who underwent fusion to assess the frequency, timing, and causes of death, the 3-year cumulative mortality rate post-fusion was 1.93% and analgesic-related deaths were responsible for 21% of all deaths and 31.4% of all potential life lost. (Juratli, 2009) A study to compare the surgical experience, clinical outcomes, and effect on body weight between obese and morbidly obese patients undergoing lumbar spine fusion surgery concluded that clinical outcomes were independent of the BMI of the patient, but the incidence of postoperative complications was significant in 45% of morbidly obese and 44% of obese patients. The authors proposed that morbidly obese patients should undergo bariatric surgery before spine surgery in nonemergent situations. (Vaidya, 2009) For nonradicular low back pain with common degenerative changes, there is fair evidence that fusion is no better than intensive rehabilitation with a cognitive-behavioral emphasis for improvement in pain or function, and less than half of patients experience optimal outcomes (defined as no more than sporadic pain, slight restriction of function, and occasional analgesics) following fusion. (Chou, 2009) Posterolateral bone-grafting fusion is not necessary when

a Denis type-B thoracolumbar burst fracture associated with a load-sharing score of ≤ 6 is treated with short-segment pedicle screw fixation. (Dai, 2009) Discography (and not merely the fusion) may actually be the cause of adjacent segment disc degeneration. This study suggested that the phenomenon of accelerated adjacent segment degeneration adjacent to fusion levels may be, in part, explained by previous disc puncture if discography was used in segments adjacent to the fusion. (Carragee, 2009) Among Medicare recipients, the frequency of complex fusion procedures for spinal stenosis increased 15-fold in just 6 years. The introduction and marketing of new surgical devices and financial incentives may stimulate more invasive surgery. (Deyo-JAMA, 2010) Results of this study suggest that postmenopausal female patients who underwent lumbar spinal instrumentation fusion were susceptible to subsequent vertebral fractures within 2 years after surgery (in 24% of patients). (Toyone, 2010) 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. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

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) A recent case-control study of lumbar fusion outcomes in worker's compensation (WC) patients concluded that only 9% of patients receiving WC achieved substantial clinical benefit compared to 33% of those not receiving WC. (Carreon, 2009) This large historical cohort study suggests that lumbar fusion may not be an effective operation in workers' compensation patients with disc degeneration, disc herniation, and/or radiculopathy, and it is associated with significant increase in disability, opiate use, prolonged work loss, and poor RTW status.

(Nguyen, 2010) After controlling for covariates known to affect lumbar fusion outcomes, patients on workers' comp have significantly less improvement. (Carreon, 2010)

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) A comparison of surgical and nonoperative outcomes between degenerative spondylolisthesis and spinal stenosis patients from the SPORT trial found that fusion was most appropriate for spondylolisthesis, with or without listhesis, and decompressive laminectomy alone most appropriate for spinal stenosis. (Pearson, 2010)

Lumbar fusion for Scheuermann's kyphosis: Recommended as an option for adult patients with severe deformities (e.g. more than 70 degrees for thoracic kyphosis), neurological symptoms exist, and pain cannot be adequately resolved non-operatively (e.g. physical therapy, back exercises). Good outcomes have been found in a relatively large series of patients undergoing either combined anterior-posterior or posterior only fusion for Scheuermann's kyphosis. (Lonner, 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)

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)