

Notice of Independent Review Decision

DATE OF REVIEW:

07/20/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Lumbar 360 degrees Mini L5/S1 with one day length of stay

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

Board Certified Orthopaedic Surgeon

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

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 requested procedure (360 degrees Mini L5/S1 with one day length of stay) is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 07/13/10 letter from Attorneys At Law, P.C.
- 07/08/10 MCMC Referral
- 07/08/10 Notice To Utilization Review Agent of Assignment, DWC
- 07/08/10 Notice To MCMC, LLC Of Case Assignment, DWC
- 07/06/10 letter from attorney
- 07/06/10 Confirmation Of Receipt Of A Request For A Review, DWC
- 06/07/10 Request For A Review By An Independent Review Organization
- 05/11/10 Reconsideration/Appeal of Adverse Determination letter, HDi
- 04/27/10 Utilization Review Determination letter, HDi
- 04/06/10 Surgery Scheduling Slip/Checklist
- 03/19/10 MRI lumbar spine,
- 03/08/10, 03/27/09 Consultation, M.D., Back Institute
- 02/10/10 Rx Guardian Results Report,
- 02/08/10 Cope Program Evaluation, M.D., Back Institute
- 10/20/09 Office Note, M.D., Back Institute
- 07/17/09 New Patient Consultation, M.D., Back Institute
- 07/17/09 Outpatient Psychotherapy Note, M.S., L.P.C., Cope
- 06/19/09 Operative Report, M.D., Hospital
- 05/27/09 (faxed date) handwritten chart note

- 05/20/09 memo from WC Case Coordinator, Back Institute, with handwritten note
- 05/19/09, 12/29/09 Assigned Designated Doctor's Evaluation and Report, M.D., DWC
- 05/13/09 Behavioral Medicine Evaluation/Pre-Surgical Screening, M.S., L.P.C., Cope
- 05/25/10, 04/17/09, 04/10/09, 03/27/09 Radiology Reports, M.D., Back Institute
- 04/10/09 to 05/25/10 Followup notes, M.D., Back Institute
- 03/31/09 Functional Capacity Evaluation, MS, PT,
- 03/18/09 MRI lumbar spine, Imaging
- 11/26/07 MRI lumbar spine
- Undated, unsigned patient information sheet, Back Institute
- Undated Case Management: Thoracic and Lumbar note
- Undated Rebuttal to denial letter,
- ODG TWC Low Back guidelines

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is male who was reported to have sustained a work-related injury on xx/xx/xx. There is no initial documentation of treatment immediately after injury or the Employer's First Report of Injury. The majority of the medical record is after referral to the spine specialist, Dr. of the Back Institute. There is however a report of a MRI dated 11/28/2007 which is prior to the alleged work injury. This MRI reported L5-S1 disc degeneration, diffuse disc bulge and mild spondylolisthesis with bilateral L5 spondylolysis and severe bilateral foraminal stenosis. The recorded diagnosis for the MRI was lumbosacral neuritis. This was obtained prior to the work-related incident and clearly documents a history of prior back problems for which the injured individual sought medical care and enough symptoms to warrant the imaging study. It should be noted that the injured individual related a history of injury in August and October 2008, but sought no medical attention until the injury on xx/xx/xx. The described mechanism of injury was when his back locked up. He was subsequently referred to Dr.. Treatment has included medications, selective nerve root block, physical therapy, off work, work conditioning, and evaluation for a pain management program. The injured individual's primary complaint has been pain. M.D. on 12/17/2009 on Designated Doctor Examination opined that the extent of injury was a lumbar sprain/strain with an aggravation on the underlying spondylolisthesis. He had placed the injured individual at Maximum Medical Improvement on 05/14/2009 with a zero per cent whole person impairment rating. The injured individual continued with symptoms despite extensive evaluation and treatment. Functional capacity evaluation performed on 03/31/2009 reported poor aerobic fitness level and a light-medium physical demand level (PDL) level. The injured individual has not returned to work in any capacity since injury. recommended that the injured individual was clear for surgery, but noted only a fair to good prognosis. She reported on 07/17/2009 that the injured individual still had a medium level of dysfunction, mild level of depression, and a mild level of entitlement. Dr. recommended the injured individual undergo a 360 degree mini L5/S1 fusion. He reported that he noted a translation from 10 mm to 15 mm on flexion/extension views of the lumbar spine on 05/25/2010. The requested procedure was denied upon initial review on 04/27/2010 because of the lack of psychological screening. The reconsideration/appeal was upheld on 05/11/2010 because of the lack of documentation of any evidence of spinal instability. Both reviewers cited the Official Disability Guidelines as the basis of their opinions.

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

The injured individual is a male who alleges a work-related injury on xx/xx/xx as a result of a push/pull type of mechanism of injury. The medical documentation reviewed clearly supports a prior history of significant back problems to include a MRI dated 11/28/2007 with a diagnosis of lumbosacral neuritis as the reason for the study. This MRI is not significantly different from the one performed on 03/18/2009. There is no evidence of neural impingement. The spondylolysis and spondylolisthesis were present prior to the alleged work incident. The injured individual has undergone significant evaluation and treatment with continuing symptoms which are primarily pain. In addition, though it has been reported that he has decreased his use of tobacco products, he is still actively smoking. A drug screen done on 02/08/2010 was inconsistent and has never been adequately addressed. The psychological assessment still shows significant confounding variables which have not been rectified.

Both the evidence-based Official Disability Guidelines and Medical Disability Advisor recommend investigation and addressing of nonphysical factors (psychosocial, workplace, socioeconomic) in cases of delayed recovery or return to work. The injured individual continues to use tobacco products, has disability greater than six months, is not involved in an active rehabilitation program and has not returned to work in any capacity since the injury. In addition, an inconsistent drug screen has never been addressed. The requested procedure does not meet the Official Disability Guidelines and Medical Disability Advisor criteria.

The injured individual had been placed at maximum medical improvement (MMI) and given a zero percent impairment rating. Department of Workers Compensation (DWC) guidelines note that certification of MMI implies that further active treatment in all medical probability is unlikely to result in significant improvement or change in functional status. A zero per cent impairment rating implies no permanent impairment as a result of the compensable injury and no evidence of neurological compromise.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

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)

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.)

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) 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)

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)

THE MEDICAL DISABILITY ADVISOR