



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WC

DATE OF REVIEW: 3-9-09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Lumbar posterior decompression revision L3-L4, lumbar posterior fusion with instrumentation L3-L4, allograft infuse, autograft ICBG, removal of hardware agile rod, LOS x 3 days.

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

American Board of Orthopedic 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

- MD., office visits from 3-9-07 through 1-7-09, for a total of 18 visits.
- 3-13-07 CT scan of the lumbar spine.
- 5-21-07 Surgery performed by Dr.
- MD., office visits on 4-30-08 through 10-23-08, for a total of 3 visits.
- 10-16-08 left L2 and left L3 selective nerve root injection and transforaminal ESI.
- 1-21-09 MD., Utilization Review.
- 2-2-09 MD., Utilization Review.
- 2-23-09, MD., provided a letter.

PATIENT CLINICAL HISTORY [SUMMARY]:

On 3-9-07, the claimant was evaluated by MD. The claimant is seen for low back pain and bilateral lower extremity weakness with walking. The claimant had a fusion in 1992, but his pain has never been this bad. The claimant reports that 80% of his pain is in his back. X-rays showed no instability. The claimant had a solid appearing arthrodesis at L4-L5 with disc collapse at L3-L4 and L5-S1. A lumbar MRI showed spinal stenosis at L3-L4 and to a lesser degree at L2-L3 and L5-S1. The evaluator recommended a CT scan to complement the MRI scan. The evaluator felt that ultimately the claimant will need decompression at L3-L4 and possibly at L2-L3 as well. He will need L5-S1 addressed as well.

3-13-07 CT scan of the lumbar spine shows postsurgical change of the lower lumbar spine appears to be a L4-L5 and possibly L5-S1 discectomy, with bone intertransverse fusion bilaterally at L4-L5, and on the left at L5-S1. Spondylotic changes are seen elsewhere as described with moderately severe central canal stenosis seen at the L3-L4 level. Note there are scars in the L5 and S1 vertebrae from removal of pedicle fixation Screws.

On 3-19-07, the claimant was evaluated by Dr. He is seen for follow up of his CT scan. He has severe stenosis at L3-L4. The claimant has a solid intertransverse and facet joint fusion at L4-L5. The L5-S1 papers to be solid on the left. The claimant continues to have severe buttock and lower extremity pain consistent with L3-L4 dermatomes. The claimant has not undergone aquatic therapy recommended. The claimant was taken off work. The evaluator also recommended an L3-L4 cortisone injection.

Follow-up visits with Dr. noted the claimant was not progressing with treatment. Therefore, surgery was recommended.

On 5-21-07, the claimant underwent posterior lumbar decompression via partial laminectomy of L3, partial laminectomy of L4, partial facetectomy of L3-L4 bilaterally, foraminotomy L3-L4 bilaterally. Segmental posterior spinal instrumentation with CDH Legacy screws and agile rods bilaterally.

Postoperative office visit with Dr. notes the claimant improved dramatically regard to his symptoms. The claimant was doing well.

On 8-13-07, the claimant was evaluated by Dr. He returns doing about the same. He continues to have right buttock pain and it was felt to be radicular in nature. If he does not respond to physical therapy, the claimant will be provided with along acting opioid. The evaluator recommended consultation with pain management specialist if a local injection versus and ESI.

On 9-10-07, the claimant was evaluated by Dr. The claimant was doing better. His pain is improving. The evaluator recommended a work hardening/conditioning program.

On 10-8-07, the claimant was seen by Dr. it is noted the claimant has satisfactory position of the instrumentation with no evidence of loosening. The claimant is not tolerating work as well. He was continued on his restrictions.

On 12-3-07, Dr. notes the claimant was doing better. He has got good mobility and normal gait pattern. The claimant was continued on work restrictions. He could increase some of the lifting.

Follow-up with Dr. on 1-18-08 notes the claimant is using more narcotics with less effectiveness. The evaluator reported that the rods can and sometimes break. The majority of his symptoms were in his back and not in his legs. X-rays were obtained which showed satisfactory position of the instrumentation and no evidence of the bumper breaking. The claimant is continued on his exercises as well as full time regular work. The claimant is tried on Ultram ER.

Follow-up with Dr. on 4-30-08 notes the claimant is in after completing a right L2-L3 selective nerve root blocks with transforaminal ESI. The claimant reports he is almost pain free. Nothing further was advised. He could continue to use Norco as needed.

On 5-7-08, the claimant was evaluated by Dr. The claimant was doing about the same. He had low back pain, but was tolerating it. X-rays showed the agile rod from Sofamor Danek. It appears to be intact and is holding fast.

On 8-20-08, the claimant was evaluated by Dr. for medication reassessment. The claimant is continued on Hydrocodone 10/325 mg one po a 5 hours.

On 10-16-08, the claimant underwent a left L2 and left L3 selective nerve root injection and transforaminal ESI.

On 10-23-08, the claimant was evaluated by MD. The claimant reported that after the second injection he has done well. The claimant was evaluated for his hip by Dr. and was found to have avascular necrosis bilaterally. Dr. does not recommend any surgical intervention at this time.

On 11-30-08, the claimant was evaluated by MD., the claimant reports he has done fairly well. He does not have any leg pain. X-rays show the claimant has a agile rod. It is clear that in the right side agile rod, the cable has broken. The left side appears to be intact. The evaluator recommended revision procedure or simply wait and observe. The claimant would like to avoid any additional treatment at this time.

On 1-7-09 MD., evaluated the claimant. The claimant is having increased symptoms of lower back pain and some into the left lower extremity. He has a known fracture of the agile rod that was placed a year and a half ago. He had previously done fairly well with it, but presently it is beginning to become increasing symptomatic. The evaluator discussed revision surgery with him previously. He is now prepared and desiring to do that.

On 1-21-09, MD., UR denial of services- even though the requested procedure will likely be needed, the records indicate the claimant was a smoker which is a relative contraindication to a fusion surgery electively, especially given the history of prior surgery to his same area of the spine. The claimant has not had any progression of his neurological dysfunction that would warrant a more urgent surgery before tobacco use cessation for several weeks.

On 2-2-09 MD., performed a Utilization Review,. Denial of requested appeal for lumbar posterior decompression, revision of L3-L4 lumbar posterior fusion with instrumentation. The evaluator reported that under current guidelines, the use of a fusion is not recommended in the absence of instability. The claimant has no documented instability. A psychological evaluation is recommended prior to surgery.

On 2-23-09, MD., provided a letter. The evaluator requested a reevaluation of the case for Mr. It is the claimant's understanding that the claimant's revision surgery has been denied on the basis of fusion not being recommended in the absence of instability and that the patient has not had a psychological evaluation. It is certainly true that the patient has not had a psychological evaluation. The evaluator did not feel one was

necessary in his case; however, if that is deemed necessary, I will be glad to request that. However, the evaluator felt the statement that fusion is not recommended in the absence of instability is grossly inaccurate. The claimant has failed posterior lumbar instrumentation, which would indicate a failed fusion at the L3-L4 level. This procedure was approved previously by Workers' Compensation and was performed under Workers' Compensation. The current recommendation for a claimant who has severe back pain, in fact worsening back pain in his case along with some lower extremity symptoms and evidence of instrumentation failure is that the instrumentation is revised and fusion revised if necessary. The evaluator would submit that, which is considered standard of care and to do something less would be less than standard of care. The evaluator felt that denial of revision surgery in this claimant is an egregious mistake on the part of Corvel Corporation.

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

BASED ON THE AVAILABLE MEDICAL RECORDS, THE REQUESTED PROCEDURE IS DENIED DUE TO LACK OF ADEQUATE DOCUMENTATION. THERE IS LACK OF FLEXION/EXTENSION X-RAYS DOCUMENTING INSTABILITY AT THE L3-L4 LEVEL AND THERE IS ABSENCE OF PSYCHOLOGICAL EVALUATION, AS REQUIRED IN CURRENT TREATMENT GUIDELINES. ADDITIONALLY, DUE TO THE ABSENCE OF A CT SCAN OF THE L3-L4 AREA TO SUPPORT THE PROPOSED PROCEDURE. WITHOUT OBJECTIVE EVIDENCE OF INSTABILITY/PSEUDOARTHROSIS, AND THE CLAIMANT'S SMOKING HABIT, APPROVAL FOR LUMBAR POSTERIOR DECOMPRESSION REVISION L3-L4, LUMBAR POSTERIOR FUSION WITH INSTRUMENTATION L3-L4, ALLOGRAFT INFUSE, AUTOGRAFT ICBG, REMOVAL OF HARDWARE AGILE ROD, LOS X 3 DAYS CANNOT BE CERTIFIED.

ODG-TWC, last update 2-19-09 Occupational Disorders of the Lumbar Spine – Lumbar 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) 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)

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)

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 disectomy. [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)