



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

DATE OF REVIEW: 5-13-09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L4-L5 and L5-S1 posterior lumbar interbody fusion

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

- 8-15-08 MRI of the lumbar spine.
- MD., office visits from 8-21-08 through 10-30-08 (4 visits).
- 9-5-08 EMG/NCS performed MD.
- office visits from 11-6-08 through 2-4-09 (4 visits).
- 1-9-09 MRI of the thoracic spine.
- 1-14-09 Surgery performed, MD.
- 1-26-09, a lumbar myelogram and post CT scan.
- 3-6-09 MD.
- 3-26-09 Utilization Review Denial
- 4-27-09 Utilization Review Denial

PATIENT CLINICAL HISTORY [SUMMARY]:

MRI of the lumbar spine dated 8-15-08 showed an HNP at L4-L5, more focal in the midline, which combines with capsular and ligamentous hypertrophy to cause moderate to severe narrowing of the central canal and both lateral recesses, with potential impingement of the L4 root. Moderate disc bulging at L5-S1 about the exiting S1 nerve roots in the lateral recess and L5 roots in the foraminal but causes no obvious displacement or compression.

xx-xx-xx MD., the claimant is a female with complains of low back pain and left hip and left leg pain following an injury at work. The claimant reported that her pain worsened while she was driving. The claimant rated her pain as 10/10. On exam, the claimant has tenderness to palpation at the lumbar spine. No instability. DTR are symmetric in the upper and lower extremities. SLR is negative bilateral. Gait is abnormal and slow. Left thigh sensation is decreased. The evaluator recommended referral to Dr. for electrodiagnostic studies. The claimant deferred Medrol due to diabetes. It was uncertain if she was a surgical candidate. The claimant was provided with a prescription for Lortab and Lidoderm patches.

9-5-08 EMG/NCS performed MD., showed evidence of left sided L4-L5 radiculopathy along with right sided S1 radiculopathy.

Follow-up visit with Dr. on 9-10-08 notes the claimant reported worsening of low back pain that radiates into the left hip and left leg. She takes Lortab 4 a day without pain relief. The Lidoderm patches helps. There is no weakness or numbness on examination. The evaluator reported that her physical exam, EMG/NCS and MRI are consistent with L4-L5 radiculopathy. The claimant was continued on Lortab and referred to Dr. for epidural steroid injection.

Follow-up with Dr. on 10-30-08 notes the claimant reported she was worse. She had seen Dr. who prescribed Neurontin. The claimant reported that her pain worsened with physical therapy. The claimant reported she fell 2 weeks ago. On exam, the claimant had decreased strength in plantar flexion and dorsiflexion on the left. The claimant was continued on Lortab and Neurontin and was referred for surgical consultation.

On 11-6-08, the claimant was evaluated MD. The evaluator reviewed the medical records provided. He recommended the claimant undergo left L4 hemilaminectomy with partial discectomy.

On 1-7-09, Dr. reported that the claimant disc herniation does not account for her significant weakness and hip flexion. She does however have significant diabetes mellitus that would account for some of her polyradiculopathy. The evaluator recommended an MRI of the thoracic spine for possible lesion in this area that would account for such weakness in her hip flexion. The claimant also has significant muscle wasting in the area of her quadriceps. The evaluator would also like to speak with the neurologist that performed the EMG to see his recommendations.

MRI of the thoracic spine dated 1-9-09 shows a mild anterior osteophyte formation at multiple levels.

1-14-09 Surgery performed MD. L4-L5 left hemilaminectomy with partial discectomy.

Follow-up with Dr. on 1-21-09 notes the claimant has little improvement. She complains of left leg weakness. She denies any back pain. She reports no hip extension. The claimant underwent left L4-L5 hemilaminectomy with partial discectomy on 1-14-09. The staples were removed. Her neurologic exam was a little better, but still has left leg pain and weakness in the left hip extension 05/ (no change) left knee extension 3/5 (slightly improved), left ankle extension 3/5 (slightly improved). The claimant was provided with a prescription for Lyrica. The evaluator recommended a CT myelogram and referred for a second opinion.

On 1-26-09, a lumbar myelogram shows bilateral extradural defect at the L4-L5 level more marked on the left side probably due to recurrent disc herniation. Post CT scan shows laminectomy on the left side at L4-L5 level with a diffuse disc bulge with recurrent disc herniation in the central on both sides, more marked on the left with obliteration of epidural fat and impingement on the thecal sac. Laminectomy changes at the L5-S1 level on the left side without any evidence of recurrent disc herniation. Central spinal canal, lateral stenosis at the L4-L5 level due to diffuse disc bulge,

recurrent disc herniation, facet arthropathy on the right side. Mild degree of lateral recess stenosis bilaterally at the L5-S1 level. No evidence of spondylolysis or spondylolisthesis. No evidence of arachnoiditis.

On 2-4-09, Dr. reviewed the claimant myelogram and post CT scan. The evaluator reported that the claimant has chronic disc herniation at L4-L5 and L5-S1 which could not be relieved with small surgery, attempted hemilaminectomy at L4-L5 and L5-S1 was completely unsuccessful. The claimant continues with severe pain. Therefore, the evaluator recommended a complete facetectomy at L4-L5 and L5-S1 removing the entire chronic appearing disc and then do an L4-L5 and L5-S1 fusion.

On 3-6-09, the claimant was evaluated by MD. It is noted the claimant has persistent back and lower extremity pain for nine months. The claimant is ambulating with a walker. On exam, the claimant has SLR is positive on the left. Bilateral Lasegue's to 40 degrees. Fabere's is negative. The claimant has weakness of the tibialis anterior and extensor longus being 4/5 on the left. The evaluator recommended a two level fusion at L4-L5 and L5-S1.

3-26-09 Utilization Review Denial - Documentation does not show there was relief of symptoms after first surgery, there is no ODG indication. There is no documented instability, preop psych evaluation, no confirmation that all pain generators have been identified. Physician advisor attempted a peer to peer with Dr.

4-27-09 Utilization Review Denial - there is no documentation of instability. The patient has chronic low back pain and radiculopathy since prior discectomy. Physician advisor attempted a peer to peer with Dr. 4-21-09, but spoke with someone from his office who stated the claimant got second opinion from another Spine surgeon and this fusion recommended. Requested her to second opinion but without indication for arthrodesis this procedure is not indicated as requested.

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

The claimant's clinical complaints have not been fully evaluated. There is no documented evidence of instability. There needs to be a psychological evaluation with formal testing. The clinical complaints and the diagnostic test are not correlated well.

The records show weakness of hip flexion, which is not explained by the area of surgery at L4/L5 with recurrent disc herniation. Neurological re-evaluation needs to be performed in light of diabetes to determine if neuropathy is due to diabetes.

Claimant does have recurrent HNP which will need to be addressed, therefore a two level fusion is not recommended. Therefore, the request for L4-L5 and L5-S1 posterior lumbar interbody fusion is not certified.

ODG-TWC, last update 5-11--09 Occupational Disorders of the Low Back –

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) 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) 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)**