

**IRO NOTICE OF DECISION – WC**

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**Claims Eval**

Notice of Independent Review Decision

**IRO REVIEWER REPORT - WC**

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**Date notice sent to all parties:** July 24, 2012

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Inpatient L3-4 Revision Lumbar Surgery, Hardware Removal, Exploration of Arthrodesis, L4-4-S1 Revision Lumbar Laminectomy Discectomy, Fusion w/ Instrumentation, w/ 2 day inpatient length of stay, and implantable bone growth stimulator.

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

American Board of Orthopaedic Surgery

**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 medical necessity exists for each of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

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**PATIENT CLINICAL HISTORY [SUMMARY]:**

xxxxx MD, preoperative diagnosis: Failed lumbar syndrome with HNP instability L2-3, L3-4, L4-5 and L5-S1. Postoperative diagnosis: Failed lumbar syndrome with HNP instability L2-3, L3-4, L4-5 and L5-S1. No herniated nucleus pulposus L2-3 although stenosis. Procedure: Examination under anesthesia and pain study. Revision lumbar spine surgery with laminectomy, excision of scar tissue, discectomy and neural LHL602.

foraminotomy L5-S1 bilaterally, additional inter space L4-5 bilaterally, additional inner space L3-4 bilaterally. Revision sacral spine surgery first sacral interval bilaterally with decompression of the cauda equine and neural foraminotomy at the S1 nerve roots. Revision lumbar spine surgery L2-3 bilaterally with decompression of the cauda equina and neural foraminotomy at both L2 nerve roots with exploration of L2-3 disc space. Micro dissection technique. Harvesting and preparation of bone graft. Intraoperative discogram L5-S1 positive. Intraoperative discogram L3-4 positive. Intraoperative discogram L2-3 negative. Reduction of subluxation L3-4. Anterior arthrodesis L3-4. Anterior arthrodesis L4-5. Anterior arthrodesis L5-S1. Lateral arthrodesis. Cage placement L3-4 on the right. Posterior instrumentation non segmental fixation, L3 bilaterally, L4 bilaterally with the use of compression technique bilaterally and cross link L3-4. Primary repair of dural tear with laminectomy and free graft.

xxxx MD, the claimant is fifteen days post op. Exam shows absent posterior tibial tendon jerks. Impression: Failed lumbar spine syndrome post reconstruction. Postoperative ileus requiring hospitalization and nasogastric tube x5 days. Plan: Initiate his exercise program.

xxxx MD, the claimant follows up. Exam shows absent posterior tibial tendon jerks. Impression: Failed lumbar spine syndrome post reconstruction. Plan: Post op physical therapy.

xxx MD, the claimant follows up. His physical therapy has been granted. Exam shows absent posterior tibial tendon jerks. Impression: Failed lumbar spine syndrome post reconstruction. Plan: Physical therapy with functional capacity evaluation.

xxxx MD, the claimant follows up. Exam shows absent posterior tibial tendon jerks. Impression: Failed lumbar spine syndrome post reconstruction. Plan: Return to full duty work.

Follow up with MD, on xxxx, the claimant follows up. Exam shows absent posterior tibial tendon jerks. Impression: Failed lumbar spine syndrome post reconstruction with adjacent segment disease radio graphically with good response to conservative treatment. Plan: Continue conservative treatment.

xxxx MD, the claimant complains of being shorter now than he was 2 years ago. He was 5'11" and now he is 5'9". He also complains of left knee pain. X-rays of his pelvis reveal hips without degenerative joint disease, sacroiliac joints without sclerosis. X-rays of his lumbar spine to include flexion-extension views reveal L2 to S1 decompression with L2-L3 functional spinal unit collapse, L3-L4 global instrumented arthrodesis with L4-L5 and L5-S1 decompression with no motion on flexion-extension views. Exam shows absent posterior tibial tendon jerks. Physical examination of his left knee is consistent with chondromalacia patella without meniscal pathology. Impression: Chondromalacia patella. Failed lumbar spine syndrome adjacent segment disease with primarily lumbago. Plan: He would benefit from chronic pain management.

xxxx PNL: We are disputing entitlement of Left Knee because: Carrier denies that your compensable injury of the lumbar spine on xxxxx extends to or includes the left

knee as there is no injury to the left knee that occurred within the course and scope of your employment. Furthermore there has been no prior mention or treatment of the left knee. Carrier is accepting a lumbar sprain/strain with HNP at level L2-3, L4-5 and L5-S1.

xxxx PNL: We are disputing entitlement of benefits for the left knee and erectile dysfunction because: Carrier denies that your compensable injury of the lumbar spine on xxxx extends to or includes the left knee as there is no injury to the left knee that occurred within the course and scope of your employment. Furthermore there has been no prior mention or treatment of the left knee. Carrier denies that your compensable injury of the lumbar spine on xxxxx extends to or includes the diagnosis and treatment of erectile dysfunction as there is no medical evidence to show a causal link between the injury and diagnosis of erectile dysfunction. Carrier is accepting a lumbar sprain/strain with HNP at level L2-3, L4-5, and L5-S1.

Follow up with MD, on xxxxx, the claimant complains of back stiffness with erectile dysfunction and rectal incontinence. Exam is unchanged. Impression: Failed lumbar spine syndrome with chronic pain with good response to injections. Erectile dysfunction related to his lumbar spine. Rectal incontinence related to his lumbar spine. Plan: Continue conservative treatment and exercise program.

Follow up with MD, on xxxx, the claimant follows up. Exam is unchanged. Impression: Failed lumbar spine syndrome with progressive cauda equina symptoms. Plan: Get MRI of his lumbar spine.

xxxx MRI of the lumbar spine interpreted by MD, showed a normal MRI appearance of the lumbar spine.

Follow up with MD, on xxxx, the claimant complains of back pain and leg pain bilaterally, greater on right than left. Exam is unchanged. Impression: Failed lumbar spine syndrome with partial cauda equine syndrome with failure of conservative treatment.

xxxx Lower EMG/NCV interpreted by MD, showed there is residual radiculopathy from L3 through S1 roots bilaterally with the greater on the left with acute irritability in the L5 and S1/2 distributions. This is confirmed by absent tibial reflexes and delayed peroneal F-waves. The lower sacral S2-S4 motor roots are significantly involved at a 2 level with some polyphasicity and there is perirectal numbness as well, indicative that his spinal injury has resulted in his bowel bladder incontinence and erectile dysfunction.

xxxx Lumbar myelogram interpreted by MD, showed pedicle screws, plate and interlocking rods are noted at the L3-4 level. Spondylitic changes are seen throughout as well. There is mild narrowing and deformity of the thecal sac at the L4-5 level.

xxxxx Post myelogram CT of the lumbar spine interpreted by MD, showed solid anterior and posterior fusion at L3-4. Ossifications within the left lateral recesses of L4-5 and L5-S1 producing compression of the left L4 and L5 nerve roots in the neural foramina and left L5 nerve root in the lateral recess. Right-sided foraminal stenosis at L4-5 and L5-S1. Increased soft tissue in the ventral epidural space posterior to the L4 and L5

vertebral bodies. Disc material versus scar or epidural lipomatosis. MRI may be useful for further evaluation if clinically appropriate.

xxxxx MD, performed a medical records review. These records do not change my previous opinions or reports. There remains no objective evidence of a neuroanatomical basis for incontinence or sexual dysfunction. Dr.'s EMC study does not provide objective evidence, as there are subjective interpretations by himself with no objective denervation potentials from S2 to S4 supporting his impression of an abnormal study. The patient does have postoperative changes and does have evidence of significant disk disease from prior back surgeries and from this current injury. However, there remains no objective neuroanatomical basis for his complaints of sexual dysfunction or incontinence based upon my review of these records.

xxxxxx DO, diagnosis: Lumbar HNP. Acute reaction to stress with injection. Procedure: Left L4 and L5 transforaminal epidural steroid injection. Fluoroscopic guidance and localization. IV saline lock with sedation.

Follow up with MD, on xxxxx, the claimant complains of back pain with radiation to primarily left leg. He wants to proceed with surgical intervention. Exam is unchanged.

Impression: Failed lumbar spine syndrome with recurrent HNP after two previous decompression, discectomies at L4-5 and L5-S1 with possible discogenic pain at L1-2 and L2-3 with retained hardware, instrumented arthrodesis at L3-4. Plan: Proposed surgery would be revision lumbar spine surgery with hardware removal at L3-4 and a decompression revision and instrumented arthrodesis global in nature and bone growth stimulator at L4-5 and L5-S1.

xxxxx MD., performed a Utilization Review. The claimant is a who injured his low back on xxxxxx lifting a stretcher. He has undergone previous lumbar decompression and fusion surgery L3/4 x 2. The claimant was seen on xxxxx with complaints of unremitting low back pain with radiation to primarily left leg. CT myelogram dated xxxxx reported solid anterior and posterior fusion at L3-4; ossifications within the left lateral recesses of L4-5 and L5-S1 producing compression of the left L4 and L5 nerve roots in the neural foramina and left L5 nerve root in the lateral recess; right-sided foraminal stenosis at L4-5 and L5-S1: increased soft tissue in the ventral epidural space posterior to the L4 and L5 vertebral bodies-disc material versus scar or epidural lipomatosis. Dr. notes that workup seems to indicate primarily left sided L4 and L5 nerve root symptoms secondary to the recurrent HNP at L4-5 and L5-S1 with two previous discectomies. Dr. also noted that the claimant has functional spinal unit collapse at L5-S1, instrumented arthrodesis at L3-4, global in nature with stenosis and disc bulges, possible contained herniation at L1-2 and L2-3. X-rays of the lumbar spine including flexion-extension views were noted to show L3-4 decompression with global instrumented arthrodesis with a cross link with no motion on flexion-extension views with adjacent segment disease at L4-5 and L5-S1 with functional spinal unit collapse, facet subluxation, foraminal stenosis for both anterior column deficit and posterior column deficit associated with additional adjacent segment disease at L1-2 and L2-3. There is no indication that the patient has undergone a presurgical psychological evaluation to address any confounding issues.

xxxx DO., performed a Utilization Review. The claimant is a who injured his low back on xxxx lifting a stretcher. He has undergone previous lumbar decompression and fusion surgery L3/4 x 2. The claimant was seen on xxxxx with complaints of unremitting low back pain with radiation to primarily left leg. CT myelogram dated xxxx reported solid anterior and posterior fusion at L3-4; ossifications within the left lateral recesses of L4-5 and L5-S1 producing compression of the left L4 and L5 nerve roots in the neural foramina and left L5 nerve root in the lateral recess; right-sided foramina) stenosis at L4-5 and L5-S1; increased soft tissue in the ventral epidural space posterior to the L4 and L5 vertebral bodies-disc material versus scar or epidural lipomatosis. Dr. notes that workup seems to indicate primarily left sided L4 and L5 nerve root symptoms secondary to the recurrent HNP at L4-5 and L5-S1 with two previous discectomies. Dr. also noted that the claimant has functional spinal unit collapse at L5-51, instrumented arthrodesis at L3-4, global in nature with stenosis and disc bulges, possible contained herniation at L1-2 and L2-3. X-rays of the lumbar spine including flexion-extension views were noted to show L3-4 decompression with global instrumented arthrodesis with a cross link with no motion on flexion-extension views with adjacent segment disease at L4-5 and L5-S1 with functional spinal unit collapse, facet subluxation, foraminal stenosis for both anterior column deficit and posterior column deficit associated with additional adjacent segment disease at L1-2 and L2-3. There is no indication that the patient has undergone a presurgical psychological evaluation to address any confounding issues.

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

Review of the medical records reveals a failed lumbar surgery syndrome. The records do not reflect any instability of the lumbar spine by diagnostic studies. Previous reviewers have recommended a formal psychological evaluation, which has not been provided to date.

An additional surgery is not recommended at this time based on poor prior out comes and lack of psychological evaluation that can help with prediction of outcomes. Therefore, the request for Inpatient L3-4 Revision Lumbar Surgery, Hardware Removal, Exploration of Arthrodesis, L4-4-S1 Revision Lumbar Laminectomy Discectomy, Fusion w/ Instrumentation, w/ 2 day inpatient length of stay, and implantable bone growth stimulator is not considered medically necessary.

**ODG LUMBAR FUSION UPDATED 6-29-12:** 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  $\leq 6$  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) A four-year follow-up of an RCT of instrumented transpedicular fusion versus cognitive

intervention and exercises for disc degeneration with chronic low back pain concluded that this invasive and high-cost procedure does not afford better outcomes compared with the conservative treatment approach to low back pain, and this study should give doctors pause when recommending lumbar fusion surgery without compelling indications, particularly when strong back rehabilitation programs are available. (Brox, 2010) The ECRI health technology assessment concluded that the evidence is insufficient to support lumbar fusion being more effective (to a clinically meaningful degree) than nonsurgical treatments (intensive exercise and rehabilitation plus cognitive behavioral therapy) in patients with and without prior surgery. (ECRI, 2007) There is a high rate of complications (56.4%) in spinal fusion procedures, especially related to instrumentation. (Campbell, 2011) 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, 2011) After controlling for covariates known to affect lumbar fusion outcomes,

patients on workers' comp have significantly less improvement. (Carreon, 2010) The presidents of AAOS, NASS, AANS, CNS, and SAS issued a joint statement to BlueCross BlueShield recommending patient selection criteria for lumbar fusion in degenerative disc disease. The criteria included at least one year of physical and cognitive therapy, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological comorbidities (e.g. depression, somatization disorder), and absence of litigation or compensation issues. The criteria of denying fusion if there are compensation issues may apply to workers' compensation patients. (Rutka, 2011) On the other hand, a separate policy statement from the International Society for the Advancement of Spine Surgery disagrees that worker's compensation should be a contraindication for lumbar fusion. (ISASS, 2011)

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) The latest SPORT study concluded that leg pain is associated with better surgical fusion outcomes in spondylolisthesis than low back pain. (Pearson, 2011) Comparative effectiveness evidence from SPORT shows good value for laminectomy and/or bilateral single-level fusion after an imaging-confirmed diagnosis of degenerative spondylolisthesis [as recommended in ODG], compared with nonoperative care over 4 years. (Tosteson, 2011)

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, with 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. Spinal instability criteria includes 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 correlated with symptoms and exam findings; & (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)

### **IRO REVIEWER REPORT - WC**

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**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)