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Notice of Independent Review Decision

DATE OF REVIEW: 04/10/09

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: L4-L5 anterior lumbar interbody fusion/posterior decompression, posterolateral fusion/pedicle screw instrumentation at L4-L5, length of stay

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

Board Certified Neurosurgeon

REVIEW OUTCOME

Upon independent review, the reviewer finds that the previous adverse determination/adverse determination should be:

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. MRI Lumbar Spine dated 06/16/08
2. EMG/NCV Report dated 07/02/08
3. Clinical records Dr. dated 07/22/08
4. Procedure reports dated 09/08/08
5. Clinical records Dr. dated 09/08/08
6. Clinical records Dr. dated 10/01/08 thru 11/26/08
7. Report of lumbar discography dated 11/26/08
8. Previous UR determinations dated 01/06/09 thru 03/11/09
9. Clinical records Dr. dated 01/21/09 thru 03/23/09
10. Peer review Dr. dated 01/22/09
11. Psychotherapy progress notes dated 01/29/09
12. Designated Doctor Evaluation dated 02/10/09
15. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee sustained a work injury while working for company. He claimed he slipped and fell with buckets in his hands and injured his lumbar spine, right hip, and right knee.

The employee was initially seen by , PA at on xx/xx/xx. He also complained of injuries to his right hip and right knee. He had decreased sensation at L5-S1 on examination with 1+ reflexes right lower extremity and 2+ reflexes left lower extremity. He had noted tenderness and spasms in the lumbar region with positive straight leg raise seated on the right more than left. He had no sensory changes at the right knee. Examination of the knee noted effusion, discomfort, and pain on palpation to the anterior medial and lateral components. The employee was diagnosed with lumbar radiculitis, right hip pain, and right knee pain. He was given pain medications and therapy began.

The employee continued follow-up with the same clinic.

On 05/09/08, a lumbar spine x-ray revealed mild degenerative hypertrophic spondylosis and disc space narrowing at L4-L5, mild bilateral facet joint hypertrophy at L5-S1, and markedly limited range of motion. A right knee x-ray revealed a small 3 mm soft tissue calcification and Hoffa's fat panel image.

The employee continued physical therapy and close follow-up.

On 06/05/08, the employee followed up at the treating clinic. He continued with a diagnosis of lumbar radiculopathy. It was noted he had improved functionally but the physical examination was consistent with prior examination. An MRI of the lumbar spine and right knee were ordered.

On 06/16/08, the employee underwent an MRI of the right knee that revealed Grade II patellofemoral chondromalacia. An MRI of the lumbar spine was performed on the same date, which showed a mild to moderate 3 mm posterior central disc protrusion at L5-S1 and mild degenerative facet hypertrophy at this level. At L4-L5, a 2 mm disc protrusion mildly impinging the thecal sac was noted. Moderate disc desiccation at L4-L5 and L5-S1 with multiple small annular tears throughout the intervertebral disc was noted. There was a mild 2mm posterior central protrusion at L2-L3. Mild degenerative hypertrophic spondylosis at L4-L5 with marrow edema along the vertebral body endplates were noted, likely degenerative in nature. Mild degenerative spondylosis at L5-S1 was also noted. Modic Type I changes at L1-L2 were noted. There was also noted to be degenerative facet hypertrophy at L5-S1.

The employee followed up with PA after the MRI, and the plan was for referral to orthopedics

On 07/02/08, the employee underwent EMG/NCV testing, which suggested a bilateral L4 radiculopathy and L5 and S1 radiculopathy on the right. Nerve conduction velocity findings suggested trauma or entrapment of bilateral peroneal nerve at the ankle.

Spine specialist, , M.D., saw the employee on 07/22/08. At that time, the employee received approximately twelve physical therapy sessions. Dr. noted a prior history of

left knee acromioplasty, and this appeared to be a transcription error and was most likely an arthroscopy. Examination of the lumbar area showed restricted range of motion with normal gait, normal heel toe walk, normal motor examination, normal sensory examination, and 2+ patellar reflexes. Achilles reflexes were 1+. Seated and supine straight leg raise was positive on the right. The diagnosis was back and leg pain with degenerative disc disease of the lumbar spine. The plan was for L4-S1 epidural steroid injections, continued physical therapy, and discogram if the pain persisted.

On 07/29/08, the employee underwent a Functional Capacity Evaluation (FCE). It was noted that his job level required a medium physical demand level, and he was currently functioning at a sedentary work level.

The employee followed up with PA after the FCE, and was released to return to work with minimal lifting requirements at that time.

On 08/29/08, the employee underwent a Designated Doctor Evaluation by Dr. . The examination on that date revealed tenderness of the lumbar spine. Supine straight leg raise was 60 degrees on the right and 90 degrees on the left. Seated was 45 degrees. There was loss of lumbar motion with normal strength. The employee had 5/8 positive Waddell's signs significant for symptom magnification. Physical therapy, pain management, and work hardening were recommended with an estimated Maximum Medical Improvement (MMI) date for three months.

On 09/08/08, the employee received a lumbar epidural steroid injection performed by Dr. . He had an additional epidural steroid injection performed on 09/30/08 without significant modulation in his pain.

On 10/05/08, an Independent Medical Evaluation (IME) was performed by , M.D. The employee had symptoms of pain and positive examination findings; however, the current treatment was felt to be somewhat excessive in nature given the diagnosis of lumbar strain and right knee pain. There was evidence of significant degenerative changes of the lumbar spine. It was noted the effects of the injury should have resolved some time ago per **Official Disability Guidelines** and MDA guidelines, approximately three to four weeks.

On 10/14/08, an additional lumbar epidural steroid injection was performed by Dr. .

The employee continued care in this fashion and did not receive significant relief from any of the therapies that were attempted thus far.

On 01/21/09, the employee was seen by Dr. , a neurosurgeon. The motor examination revealed 4/5 strength in tibialis anterior and extensor hallucis longus on the right, and was otherwise 5/5 throughout. Deep tendon reflexes were 2+ throughout and symmetrical. Plantar reflexes were normal bilaterally. Gait was antalgic. There was hypoesthetic region to the L5-S1 distribution on the right. Coordination was intact finger to nose. The MRI was reviewed as well as previous discogram. The discogram showed concordance at L4-L5 with negative concordance at L5-S1. Secondary to failure of conservative treatment including physical therapy and epidural steroid

injections, recommendations were to proceed with L4-L5 anterior lumbar fusion with posterolateral augmentation using pedicle screws posteriorly.

On 02/02/09, an additional Designated Doctor Evaluation was performed by , D.O. Dr. ' findings upheld the findings of IME, and stated the employee's diagnosis was clearly a lumbar strain and right knee sprain with right hip tenosynovitis. It was deemed the employee was at MMI on 02/10/09.

The initial review on this request was performed by Dr. . Dr. performed a peer-to-peer consultation with Dr. , D.C., who represented Dr.. Dr. noted that there was no instability documented, no preoperative psychiatric examination, and Dr. was unable to support medical necessity for a 360 degree fusion.

The appeal request was reviewed by Dr. upholding the previous denial and conducted a peer-to-peer with Dr. , D.C. Dr. noted there was no evidence of instability, the report of discography was nonspecific, and electrodiagnostic evidence was positive at multiple levels which are outside the requested surgical levels.

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

The request for L4/L5 anterior lumbar interbody fusion, posterior decompression, posterolateral fusion, pedicle screw instrumentation and length of stay is not supported by the submitted clinical information.

I concur with the previous reviewers and uphold the previous denials. The documents submitted fail to provide evidence of instability or clearly delineate that the L4/L5 disc is the employee's primary pain generator. The report of discography reports abnormal discs at two levels with concordant pain at L4/L5 and discordant pain at L5/S1. This equivocal study did not have a negative control disc and is considered invalid. The submitted records do not establish the employee meets medical necessity per the ***Official Disability Guidelines***.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

The ***Official Disability Guidelines***, 13th Edition, The Work Loss Data Institute.

Low Back: Fusion- Not recommended for patients who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction, but recommended as an option for spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, subject to the selection criteria outlined in the section below entitled, "[Patient Selection Criteria for Lumbar Spinal Fusion](#)," after 6 months of conservative care. For workers' comp populations, see also the heading, "[Lumbar fusion in workers' comp patients](#)." After screening for psychosocial variables, outcomes are improved and fusion may be recommended for degenerative disc disease with spinal segment collapse with or without neurologic compromise after 6 months of compliance with recommended [conservative therapy](#). [For spinal instability criteria, see

AMA Guides ([Andersson, 2000](#))] For complete references, see separate document with all studies focusing on [Fusion \(spinal\)](#). There is limited scientific evidence about the long-term effectiveness of fusion for degenerative disc disease compared with natural history, placebo, or conservative treatment. Studies conducted in order to compare different surgical techniques have shown success for fusion in carefully selected patients. ([Gibson-Cochrane, 2000](#)) ([Savolainen, 1998](#)) ([Wetzel, 2001](#)) ([Molinari, 2001](#)) ([Bigos, 1999](#)) ([Washington, 1995](#)) ([DeBarard-Spine, 2001](#)) ([Fritzell-Spine, 2001](#)) ([Fritzell-Spine, 2002](#)) ([Deyo-NEJM, 2004](#)) ([Gibson-Cochrane/Spine, 2005](#)) ([Soegaard, 2005](#)) ([Glassman, 2006](#)) ([Atlas, 2006](#)) According to the recently released AANS/NASS Guidelines, lumbar fusion is recommended as a treatment for carefully selected patients with disabling low back pain due to one- or two-level degenerative disc disease after failure of an appropriate period of conservative care. This recommendation was based on one study that contained numerous flaws, including a lack of standardization of conservative care in the control group. At the time of the 2-year follow up it appeared that pain had significantly increased in the surgical group from year 1 to 2. Follow-up post study is still pending publication. In addition, there remains no direction regarding how to define the “carefully selected patient.” ([Resnick, 2005](#)) ([Fritzell, 2004](#)) A recently published well respected international guideline, the “European Guidelines,” concluded that fusion surgery for nonspecific chronic LBP cannot be recommended unless 2 years of all other recommended conservative treatments – including multidisciplinary approaches with combined programs of cognitive intervention and exercises – have failed, or such combined programs are not available, and only then in carefully selected patients with maximum 2-level degenerative disc disease. ([Airaksinen, 2006](#)) For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates. ([Ivar Brox-Spine, 2003](#)) ([Keller-Spine, 2004](#)) ([Fairbank-BMJ, 2005](#)) ([Brox, 2006](#)) In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. ([Bagnall-Cochrane, 2004](#)) ([Siebenga, 2006](#)) A study on improving quality through identifying inappropriate care found that use of guideline-based Utilization Review (UR) protocols resulted in a denial rate for lumbar fusion 59 times as high as denial rates using non-guideline based UR. ([Wickizer, 2004](#)) The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. ([Weiner-Spine, 2004](#)) ([Shah-Spine, 2005](#)) ([Abelson, 2006](#)) Data on geographic variations in medical procedure rates suggest that there is significant variability in spine fusion rates, which may be interpreted to suggest a poor professional consensus on the appropriate indications for performing spinal fusion. ([Deyo-Spine, 2005](#)) ([Weinstein, 2006](#)) Outcomes from complicated surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. ([van Tulder, 2006](#)) ([Maghout-Juratli, 2006](#)) Despite the new technologies, reoperation rates after lumbar fusion have become higher. ([Martin, 2007](#)) According to the recent Medicare Coverage Advisory Committee Technology Assessment, the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with nonsurgical treatment for elderly patients. ([CMS, 2006](#)) When lumbar fusion surgery is performed, either with lateral fusion alone or with interbody fusion, unlike cervical fusion, there is no absolute contraindication to patients returning even to contact sports after complete recovery from surgery. Like patients with a thoracic injury, those with a lumbar injury should be pain free, have no disabling neurological deficit, and exhibit evidence of bone fusion on x-ray films before returning. ([Burnett, 2006](#)) A recent randomized controlled trial comparing decompression with decompression and instrumented fusion in patients

with foraminal stenosis and single-level degenerative disease found that patients universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. ([Hallett, 2007](#)) Discography may be supported if the decision has already been made to do a spinal fusion, and a negative discogram could rule out the need for fusion on that disc (but a positive discogram in itself would not justify fusion). Discography may help distinguish asymptomatic discs among morphologically abnormal discs in patients without psychosocial issues. Precise prospective categorization of discographic diagnoses may predict outcomes from treatment, surgical or otherwise. ([Derby, 2005](#)) ([Derby2, 2005](#)) ([Derby, 1999](#)) New research shows that healthcare expenditures for back and neck problems have increased substantially over time, but with little improvement in healthcare outcomes such as functional disability and work limitations. Rates of imaging, injections, opiate use, and spinal surgery have increased substantially over the past decade, but it is unclear what impact, if any, this has had on health outcomes. ([Martin, 2008](#)) The efficacy of surgery for nonspecific back pain is uncertain. There may be some patients for whom surgery, fusion specifically, might be helpful, but it is important for doctors to discuss the fact that surgery doesn't tend to lead to huge improvements on average, about a 10- to 20-point improvement in function on a 100-point scale, and a significant proportion of patients still need to take pain medication and don't return to full function. ([Chou, 2008](#)) This study showed that fusion for chronic lower back pain was the least successful common orthopaedic surgery. The study compared the gains in quality of life achieved by total hip replacement, total knee replacement, surgery for spinal stenosis, disc excision for lumbar disc herniation, and arthrodesis for chronic low back pain. For chronic lower back pain, improvements were statistically significant but clinically negligible. Although pain was reduced and function improved slightly, outcomes remained in the moderately affected range, quality of life was not improved and rendered worse, on average. While surgery for spinal stenosis and for disc herniation compare well with archetypical orthopaedic operations, the outcomes of surgery for chronic lower back pain do not even approach those of other orthopaedic procedures, and the data show that patients with back pain are rendered worse off by surgery. ([Hansson, 2008](#)) Recent studies document a 220% increase in lumbar spinal fusion surgery rates, without demonstrated improvements in patient outcomes or disability rates. ([Devo, 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, 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 discectomy. [For excessive motion criteria, see AMA Guides, 5th Edition, page 384 (relative angular motion greater than 20 degrees). ([Andersson, 2000](#)) ([Luers, 2007](#))] (3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. [For spinal instability criteria, see AMA Guides, 5th Edition, page 379 (lumbar inter-segmental movement of more than 4.5 mm). ([Andersson, 2000](#))] (4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. (5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability. (6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See [ODG Indications for Surgery -- Discectomy.](#))

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following: (1) All pain generators are identified and treated; & (2) All physical medicine and manual therapy interventions are completed; & (3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see [discography criteria](#)) & MRI demonstrating disc pathology; & (4) Spine pathology limited to two levels; & (5) [Psychosocial screen](#) with confounding issues addressed. (6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. ([Colorado, 2001](#)) ([BlueCross BlueShield, 2002](#))