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Notice of Independent Review Decision

DATE OF REVIEW: April 13, 2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Lumbar laminectomy with fusion and instrumentation L3-L4, purchase TLSO back brace, and one night length of stay.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Certified, American Board of Orthopaedic Surgery

REVIEW OUTCOME

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

☒ Upheld (Agree)

Medical documentation **does not support the medical necessity** of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who sustained a work-related injury to her low back on xx-xx-xx.

2003: On March 19, 2003, M.D., performed L4-L5 laminectomy and decompression of the nerve roots bilaterally. The postoperative diagnoses were lumbar stenosis at L4-L5 and lumbar radiculopathy.

On June 30, 2003, M.D., performed complete revision of L4 and partial revision of L5 bilateral laminectomies, revision of bilateral L4 foraminotomies, posterior spine fusion at L4-L5, L4-L5 pedicle screw instrumentation, L4-L5 transforaminal interbody fusion from the right, interbody cages, and left iliac crest bone graft.

2007: On June 19, 2007, M.D., performed left L5-S1 laminectomy, L5 and S1 root decompression with opening of lateral recesses and foraminotomies, and excision of left L5-S1 herniated disc with decompression of the L5 and S1 roots.

Postoperatively, the patient did well and no longer had left leg pain, but she did complain of residual low back pain. She was taking occasional Darvocet and Zanaflex and had increased her activities.

2008: In January, Dr. noted the patient had recurrent left leg pain and was placed on Cymbalta by Dr.. She had a left antalgic gait and was not working. She did not want a left L5-S1 epidural steroid injection (ESI) because she had reactions to the medications.

Magnetic resonance imaging (MRI) of the lumbar spine demonstrated minimal disc bulge at L1-L2, broad-based disc bulge at L2-L3 with disc encroachment on the inferior aspect of the neural foramina bilaterally resulting in bilateral narrowing and ligamentous thickening and facet disease, broad disc bulge at L3-L4 with ligamentous thickening and facet disease resulting in moderate central spinal stenosis and severe bilateral neural foraminal stenosis (right greater than left), bilateral neural foraminal stenosis more prominent on the right at L4-L5, broad-based disc bulge at L5-S1 with bilateral neural foraminal stenosis (mild on the right and moderate on the left).

The patient continued to have severe chronic mechanical low back pain with radiating hip and leg pain bilaterally. Dr. prescribed hydrocodone and Prevacid. He recommended a lumbar myelogram and CT scan which was denied.

In December, Dr. noted the patient had not been able to work since September because of her pain. She walked with a flexed posture to the low back with a bilateral antalgic and wide-based gait with bilateral straight leg raising positive at less than 45 degrees. She continued to require hydrocodone. Lumbar spine x-rays showed retrolisthesis of L3 on L4 with narrow disc space posteriorly and a wide disc space anteriorly, indicating significant instability.

2009: On January 21, 2009, computerized tomography (CT) of the lumbar spine with post myelogram CT demonstrated a previous left laminectomy at L4-S1, soft tissue mass-like density in the surgical defect and posterior to the left S1 nerve root. There was soft tissue density between the disc space and the thecal at L5-S1, previous laminectomy and partial facetectomy at L4-L5 with pedicle screws and interbody fusion components, mild enhancing scar tissue at L4-L5, mild central canal stenosis at L3-L4 of uncertain clinical significance.

Dr. suspected unstable L3 level with retrolisthesis and wide disc space anteriorly and a narrow disc space posteriorly. He discussed treatment options including a trial spinal cord stimulator (SCS) and ESI. The patient did not want to have either.

On February 12, 2009, the patient reported severe back pain and bilateral hip and leg pain. She was taking multiple medications. Dr. discussed treatment options including a decompression and stabilization procedure at L3-L4 or a trial SCS. Because of the severe pain, she had been quite depressed. She opted to proceed with surgery as she did not want a trial SCS or ESI.

On February 20, 2009, M.D., denied the request of lumbar laminectomy with fusion and instrumentation at L3-L4, PLSO back brace, and inpatient length of stay of one night with the following rationale: "*The patient is a female who has had previous spinal surgery. It is unclear the dates of this surgeries but it is noted that she has an L4-L5 fusion and L5-S1 decompression. L3-L4 laminectomy and fusion is not medically indicated and appropriate in this female. There is no evidence of neurologic compromise, progressive neurologic deficit. It is unclear the conservative measures which have been performed over the past three to six months within the documentation available for my review. In addition to this, there were radiographs done on December 15, 2008, which demonstrate postoperative spine with no acute abnormality. However, on February 12, 2009, there was noted instability of abnormal motion of flexion/extension per Dr.. This is not quantified in terms of millimeters or percentages, that is grade I versus II versus III; anterolisthesis versus retrolisthesis. Without further information, there are no clearcut conservative measures attempted. It appears that this as a transitional disease syndrome with previous fusion which is a complex problem, and I would not recommend a surgical intervention without exhausting conservative measures. In patient length of stay is not necessary and needed as the surgery is not necessary on needed. Thoracolumbosacral orthosis is not medically necessary or needed as the above procedure is not indicated.*"

On February 25, 2009, the patient continued to complaint of severe of mid-lumbar pain with radiating pain into the hips and down the legs with numbness, dysesthesias, and weakness in the leg secondary to her herniated disc and stenosis at L3-L4 with abnormal motion on dynamic films. Dr. stated that the patient had exhausted conservative measures including ESIs, PT, medications, and time. Instead of improving, she was getting worse. She had retrolisthesis at L3-L4 with narrowing of disc space posteriorly and wide disc space anteriorly which was very indicative of instability.

On March 9, 2009, M.D., a neurosurgeon, denied the appeal for lumbar laminectomy with fusion and instrumentation at L3-L4 with one-day stay and a purchase of TLSO back brace with the following rationale: "*The request is not supported by the submitted clinical information. The records indicate that the patient had undergone at least three operative interventions in regards to her low back. She has failed to improve with both conservative non-operative treatment and operative intervention. Dr. reports degeneration and instability at the L3-L4 level which is not described on outside imaging studies. The patient has undergone CT myelogram which makes no reference to retrolisthesis that was described by Dr.. The patient is noted to have significant stenosis at the L3-L4 level. In absence of the clinical records established that the patient has failed*

conservative treatment in the interval period from her last surgery as well as of lack of radiographic evidence of reported instability, the request cannot be certified as medically necessary."

On March 23, 2009, D.O., a family practitioner, noted back pain, loss of lordotic curvature with significant spasms at the right and left paravertebral. She assessed low back pain and recommended pre-certification of Botox 200 units for low back pain.

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

Request for the L3-4 fusion with instrumentation, purchase of TLSO back brace and one day length of stay is not indicated.

There is no documentation of structural instability. The claimant has had a number of lumbar procedures. There was no documentation of structural instability at L3-4 either rotational or translational. She has ongoing complaints of back pain. Dr. definition of instability does not appear to be supported by the records reviewed. There was no documentation of significant neurological symptoms.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Official Disability Guidelines Treatment in Worker's Comp 2009 Updates, (i.e. Low Back-Fusion and Back Brace Post Fusion)

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) 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 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)

Back Brace Post Fusion - Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable. (Resnick, 2005)