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DATE OF REVIEW: MAY 15, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Posterior lumbar interbody fusion/PISF

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

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW
OD Guidelines
MRI lumbar spine, 09/21/04
Office notes, Dr. 10/18/04, 12/06/04, 01/14/05, 03/14/05, 06/02/05, 03/03/08, 03/07/08
Electromyography report, 10/26/04
Procedure Report, 11/16/04, 02/06/08, 03/19/08, 04/22/08
Operative report, 12/30/04
ER records, 11/13/07
MRI lumbar spine, 12/12/07
X-rays lumbar spine, 12/12/07
Office notes, Dr. 01/10/08, 02/25/08
Urine Drug Screen, 01/10/08
Peer review, 02/17/08
Request for surgery, 03/07/08
Peer review, Dr. 03/14/08

Peer review, Dr. 03/21/08
Daily PT Notes, 03/12/08, 03/27/08, 03/31/08, 04/02/08, 04/07/08, 04/09/08, 04/11/08, IRO Summary, 04/30/08

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a who fell of the second rung of a ladder landing on his left hip. Lumbar spine x-rays on what appears to have been 08/02/04 revealed spina bifida occulta of L5, a sacralized L5 vertebral body which was probably a sufficient explantation for a relatively reduced disk height space since this was not a mobile segment, mild degenerative disc disease at L4-5 with slight spurring of the end plate and non-straightening of the usual lordotic curve. It was not clear if this was the claimant's body habitus. A lumbar MRI on 09/21/04 showed a severe herniated nucleus pulposus of L5-S1 with extrusion. The claimant treated for 50 percent low back and 50 percent bilateral lower extremity pain which was diagnosed as L5-S1 degenerative disc disease with pre-existing superimposed large disc extrusion and bilateral sacroiliac radiculopathy per EMG/NCV studies.

Ultimately on 12/30/04 the claimant underwent bilateral L5-S1 hemilaminotomies, lateral recess decompressions, medial facetectomy and partial diskectomies. Postoperatively he reportedly had complete relief of all of his radicular symptoms. Dr. evaluated the claimant on 01/14/05 at which time he reported that about a week postoperatively that he began to have recurrent pain and paresthesia in the lower extremities. He had equivalent back and leg pain. He was taking up to eight 5 milligram tablets of Hydrocodone a day. The incision was well-healed with some swelling under the incision. There was no drainage or symptoms of an infection. The staples were removed and he was felt to have postoperative neural swelling and post decompressive neuropathic pain. He was advised to decrease his pain medications, remain off work and attend physical therapy.

By the 03/14/05 visit he was doing quite well overall and had reduced his Norco to 1-2 tablets a day. He also had completed his physical therapy. He denied lower extremity symptoms such as pain, numbness or paresthesias, but noted intermittent mild to moderate back pain. The examination was normal. Moderate persistent mechanical low back pain was diagnosed. A functional capacity evaluation was recommended. However there is no report of such. On 06/02/05 Dr. re-evaluated the claimant for continued low back and bilateral lower extremity symptoms which were as severe as prior to surgery with pain radiating down to the lateral calves bilaterally. He had normal lower extremity strength bilaterally and absent bilateral quadriceps and Achilles reflexes. A lumbar MRI was ordered. Dr. did not feel the claimant would be able to return to unrestricted work.

The records lapse until an emergency room report which noted that on that date (xx/xx/xx) he felt something pop while pulling a 40 pound bag of dog food off a shelf. He complained of low back and bilateral leg pain. The rest of the report was unable to be interpreted.

A lumbar MRI was obtained on 12/12/07 and revealed a prior laminectomy at L5-S1 with what appears to be a residual/recurrent approximately 4-5 millimeter central disc protrusion/herniation at that level with moderate compromise of the bilateral lateral

recess and the neural foramina at that level which could well result in L5 and S1 radicular type symptoms. The spinal canal remained decompressed. There was questionably a transitional vertebral body in the lower lumbar segment. The spinal canal and neural foramina appeared near normal in caliber at the upper four lumbar levels. Lumbar spine x-rays on 12/12/07 showed a transient L5 and advanced degenerative disc disease at L4-5.

Dr. evaluated the claimant on 01/10/08 reporting numbness and tingling with pain going all the way down his leg into his calf and foot. He was taking Tramadol and Soma. The examination noted limited lumbosacral range of motion, difficulty with ankle dorsiflexion possibly due to pain, a positive straight leg raise on the left, symmetrical, but decreased reflexes bilaterally and decreased sensation in the left lower extremity when compared to the right. Dr. reviewed the 12/12/07 MRI. Back and left lower extremity radicular pain due to L5-S1 radiculopathy was diagnosed. Dr. recommended a series of epidural steroid injections and continuation of medications. A urine drug screen obtained on 01/10/08 was inconsistent for meprobamate and positive for Acetaminophen. On 02/06/08 he was given a caudal epidural steroid injection into the left lateral recess which provided about 60 percent relief. At the re-evaluation on 02/25/08 the claimant reported no relief at all with Zanaflex and reported that his insurance would not pay for Ultram. Straight leg raise was positive on the left. Bilateral lower extremity strength, sensation and reflexes were intact. Recurrent 4-5 millimeter central disc protrusion/herniation at L5-S1 which could result in L5 and S1 radicular type symptoms was diagnosed. A second epidural steroid injection was ordered.

The claimant presented to Dr. on 03/03/08 for complaints of lumbar spine pain radiating down laterally into the left foot with numbness and tingling despite physical therapy, chiropractics, medications, epidural steroid injections, and off work. The examination noted tenderness to palpation in the left lower lumbar region and down into the left posterior buttock region. He had increased pain with flexion and did not want to extend his lumbar spine as he said it would be extremely painful. He had 4/5 left anterior tibialis weakness, absent bilateral Achilles reflexes and a very positive nerve root stretch on the left at 30. Dr. reviewed the 12/12/07 MRI noting advanced disc desiccation at L5-S1, modic and endplate changes a 5 millimeter disc protrusion, moderate to severe compromise bilateral lateral recess stenosis with contact of the sacroiliac nerve roots and moderate foraminal stenosis as well bilaterally. Otherwise the L1-4 appeared relatively normal. A report of lumbar spine x-rays showed advanced degenerative disc disease at L4-5. Dr. felt that this was actually L5-S1. There was incomplete sacralization of L5; the films however where not available. The claimant was to try to obtain the MRI films. Dr. indicated the claimant had neurological findings consistent with his MRI findings.

At the 03/07/08 re-evaluation the claimant presented with the films from the 12/12/07 MRI. The claimant reported continued significant low back pain radiating down the left lower extremity and lateral aspect of the foot with numbness and paresthesias. He reported more back pain than leg pain and denied radicular symptoms on the right. The examination was unchanged from 03/03/08. Review of the MRI films noted postoperative change on the left at L5-S1, a broad based protrusion with some residual lateral recess stenosis due to the disc protrusion, moderate foraminal stenosis and significant modic endplate changes and loss of disc height. The other discs appeared normal. Possibly only a left-sided prior L5-S1 laminectomy with continued protrusion, residual stenosis and significant modic endplate changes were diagnosed. Dr.

recommended a lumbar fusion and re-exploration laminectomy and possible interbody fusion depending on if he had a bilateral laminectomy or not. He felt that the claimant's symptoms were due to the L5-S1 disc. The surgery was denied on two reviews; 03/14/08 and 03/21/08. The claimant was given a caudal epidural steroid injection in the left lateral recess on 03/19/08 and a caudal epidural steroid injection on 04/22/08. The surgical request is currently under dispute.

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

The requested posterior lumbar interbody fusion cannot be recommended as medically necessary based on a careful review of all medical records. The records indicate that the claimant had either a hemilaminectomy or a laminectomy and has a recurrent disc protrusion versus herniation causing radiculopathy. The claimant has failed conservative measures and may be a candidate for a decompressive procedure. However, there is no instability documented on flexion/extension views and no mention of instability as the cause or rationale for the proposed fusion procedure.

For these reasons the surgical request cannot be justified.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, (i.e. 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) 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)

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)**