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Notice of Independent Review Decision

DATE OF REVIEW: 12/18/2009

IRO CASE #:

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

This case was reviewed by a Orthopaedic Surgery, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L4-S1 transforaminal interbody fusion with posterior segmental fixation and a 3-day inpatient stay

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 07-08-09 Medical report from Dr.
- o 07-15-08 Medical report from Dr.
- o 08-01-08 Medical report from Dr.
- o 08-15-08 Medical report from Dr.
- o 08-21-08 Medical report from Dr.
- o 09-05-08 Medical report from Dr.
- o 09-12-08 Medical report from Dr.
- o 09-26-08 Medical report from Dr.
- o 10-28-08 Medical report from Dr.
- o 11-28-08 Medical report from Dr.
- o 12-30-08 Medical report from Dr.
- o 01-27-09 Medical report from Dr.
- o 02-27-09 Lumbar MRI read by Dr.
- o 03-06-09 Medical report from Dr.
- o 05-01-09 Medical report from Dr.
- o 05-25-09 Medical report from Dr.
- o 06-09-09 Medical report from Dr.
- o 08-04-09 Medical report from Dr.
- o 08-06-09 Initial orthopedic evaluation report from Dr. r
- o 08-09-09 PT daily progress note from PTA
- o 08-21-09 PT daily progress note from PTA
- o 08-25-09 PT daily progress note from PTA
- o 08-28-09 PT daily progress note from PTA
- o 08-31-09 PT daily progress note from PTA

- o 09-02-09 PT daily progress note from PTA
- o 09-04-09 Medical report from Dr.
- o 10-05-09 Initial Adverse Determination Letter
- o 10-19-09 Request for appeal from Dr.
- o 10-23-09 Adverse Determination Letter for Reconsideration 2-level lumbar fusion
- o 11-24-09 Request for IRO from the provider
- o 11-30-09 Confirmation of Receipt of IRO from TDI
- o 12-01-09 Notice of Case Assignment of IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a male who sustained an industrial injury to the low back when pulling a heavy object from a cabinet when it fell. When he did not improve with medication he was sent for orthopedic assessment which was conducted on July 8, 2008. He is using Wellbutrin, Coumadin and Celexa. At initial orthopedic examination he was grossly intact neurologically. X-rays showed collapse and degenerative changes of the L4-5 and L5-S1 disc spaces.

At follow-up on July 15, 2009 MRI had not yet been performed. There was suggestion of L3 or L4 radiculopathy with left leg pain and a diminished left knee reflex. Straight leg raise is positive on the left. The patient was seen on August 1, 2009. His MRI revealed a significant extruded large disc herniation consistent with his symptomatology. Epidural injections were recommended. He would need to come off his Coumadin.

A specialty consultation was provided on September 5, 2008. Treatment has been delayed due interpretation of degenerative disc condition versus acute traumatic disc condition. The MRI states, large left central subarticular disc herniation extrusion type that extrudes superiorly and compromised left lateral recess at L4-5. Clarification will be sought from an Ombudsman.

In October 2008 the patient was laid up for several weeks with about of pneumonia. He was hospitalized but on October 28, 2008 was out and using oxygen. The Ombudsman said the injury had been considered a back strain. A hearing was set for February 2, 2009. Left leg raise remained positive and recommendation continued for an epidural injection.

At reevaluation on December 30, 2009 no overt root tension signs were noted on examination. Repeat x-rays were taken and show degenerative joint disease and significant joint collapse of the hip joints.

The patient was seen on January 27, 2009. He was recommended treatment by Designated Doctor opinions. An updated MRI was desired. MRI performed February 27, 2009 revealed multilevel lumbar spondylosis. There is a left central to left foraminal disc extrusion at L4-5 with adjacent endplate osteophytes that partially compromise the left lateral recess. There is a mild broad based disc extrusion with adjacent endplate osteophytes at L5-S1. There is severe left foraminal narrowing at L4-5, moderate bilateral foraminal narrowing at L5-S1, and moderate right foraminal narrowing at L4-5.

The patient was reevaluated on March 6, 2009. He reports continuing back pain that radiates to the left leg. On examination, reflexes are intact, motor strength is intact. Left straight leg raise elicits pain. Recommendation is for a course of epidural injections.

On May 26, 2009 the patient reported little benefit with an epidural injection administered one week prior. Examination noted only tightness in the hamstrings and good hip mobility. He was recommended to go ahead with a second injection. On June 30, 2009 the patient reported little pain relief with the second epidural injection. Benefit was greater with the initial injection. Root tension signs are negative. He is referred for a spinal surgery consultation.

A surgical consultation was provided on August 6, 2009. The patient was injured more than a year prior. He has been treated with medication and two epidural injections. He has not attended any formal physical therapy. He reports constant pain that is worsening. He has a history of coronary artery disease, pneumonia and recent weight loss. He had mitral valve replacement for a bullet wound in 1969 and knee surgery in 1972. He smokes half pack of cigarettes daily. He is 6' 2.5" and 227 pounds. Lumbar motion is markedly restricted. Sensation is decreased in the left foot. Left EHL and tibialis anterior strength is 4/5; left peroneal musculature and quadriceps strength is 4+/5. Achilles reflex is diminished on the left. Left straight leg raise and sciatic tension sign are positive. X-rays reveal significant narrowing of the L4-5 disc space without any evidence of dislocation, spondylosis or spondylolisthesis. His pain is likely associated with disc herniation at the left L4-5. He will be referred for a course of therapy.

Physical therapy notes are reviewed: He was instructed in stretching (08-19-09). He is making small strides with walking and using a cane (08-21-09). He is improving with gait activities (08-25-09). He is making steady progress. He would benefit from water therapy (08-28-09). He shows some apprehension/discomfort with resistive walking in the pool (08-31-09). He is making appropriate progress for his condition (09-02-09).

The patient was most recently reevaluated in orthopedic surgery on September 4, 2009. He reports no significant relief of his pain and discomfort with a course of PT. His activity level and flexibility remain the same. Recommendation is for a two-level fusion surgery.

Request for L4-S1 transforaminal interbody fusion with posterior segmental fixation and a 3-day inpatient length of stay was considered in review on October 5, 2009 with recommendation for non-certification. Rationale for non-certification states the

patient does not have documented instability which is a criteria per ODG for a fusion procedure. Also all the pain generators are not fully clarified. It is unclear which spinal segment is the primary pain generator. A fusion would appear to be excessive. Additionally the patient has significant risk factors of mitral valve surgery, coronary artery disease and history of smoking. The only reasonable intervention would appear to be a simple decompression. It is not clear if a peer discussion was attempted.

Reconsideration was requested by the provider on October 19, 2009. The patient has a large disc herniation at L4 and another disc herniation at L5 on the left. There is significant narrowing of the disc spaces as well. While a simple decompression is reasonable, the patient's disc narrowing will likely progress after excision of the herniations which will lead to further back pain in the future. A future surgery with a fusion would then be needed. After two surgeries there would be more risk for pain from scar tissue. If this reconsideration is not allowed then request is for a lumbar laminectomy and discectomy at L4-5 and L5-S1 on the left.

Request for reconsideration, L4-S1 transforaminal interbody fusion with posterior segmental fixation and a 3-day inpatient length of stay was considered in review on October 19, 2009 with recommendation for non-certification. A peer discussion was realized.

Radiculopathy is present, but there is also significant axial back pain. MRI reveals not only disc herniations but endplate osteophytes and significant foraminal stenosis with significant facet degeneration contributing. Intervention to date appears to have been thorough and the treating physician demands smoking cessation for 6 weeks. The concern with severe facet disease is that providing adequate decompression will destabilize at least one side. As such the addition of fusion is understandable in this sort of significant decompression undertaking. However, psychological screening is a criteria per ODG and has not taken place. Surgery with fusion, therefore, cannot be recommended at this time.

Request was made for an IRO.

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

The Official Disability Guidelines criteria for lumbar fusion include, neural arch defect - spondylolytic spondylolisthesis, congenital neural arch hypoplasia. 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. Fusion procedures are not recommended 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. It is also noted that, fusion can be considered if, revision surgery for failed previous operation(s) if significant functional gains are anticipated, although 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. 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.

MRI reveals, multilevel lumbar spondylosis, a left central to left foraminal disc extrusion at L4-5 with adjacent endplate osteophytes that partially compromise the left lateral recess, a mild broad based disc extrusion with adjacent endplate osteophytes at L5-S1 and severe left foraminal narrowing at L4-5, moderate bilateral foraminal narrowing at L5-S1, and moderate right foraminal narrowing at L4-5. X-rays reveal significant narrowing of the L4-5 disc space without any evidence of dislocation, spondylosis or spondylolisthesis. The risk factors for fusion have been noted prior; i.e. history of smoking and coronary disease/medication. As noted a psychological screening is lacking. A lumbar laminectomy and discectomy at L4-5 and L5-S1 on the left would be reasonable for this patient. However, the patient does not meet ODG criteria for a fusion surgery and simple decompression would not render the spine unstable.

Therefore, my recommendation is to agree with the previous non-certification for L4-S1 transforaminal interbody fusion with posterior segmental fixation and a 3-day inpatient stay.

The IRO's decision is consistent with the following guidelines:

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 KNOWLEDGBASE

____ 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

The Official Disability Guidelines - Lumbar Chapter (12-03-2009) 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] 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.

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." 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. For chronic LBP, exercise and cognitive intervention may be equivalent to lumbar fusion without the potentially high surgical complication rates.

In acute spinal cord injury (SCI), if the spine is unstable following injury, surgical fusion and bracing may be necessary. 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. The profit motive and market medicine have had a significant impact on clinical practice and research in the field of spine surgery. 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. Outcomes from complicated

surgical fusion techniques (with internal fixation) may be no better than the traditional posterolateral fusion. Despite the new technologies, reoperation rates after lumbar fusion have become higher.

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. 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. 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. 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. 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. 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. 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. 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 ≤ 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) 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.

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.

Despite poorer outcomes in workers' compensation patients, utilization is much higher in this population than in group health. 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. Obesity and litigation in workers' compensation cases predict high costs associated with interbody cage lumbar fusion. 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.

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). 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)

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).] (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).] (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.

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.