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Notice of Independent Review Decision

DATE OF REVIEW: 10/22/09

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

Anterior interbody fusion L5-S1, anterior interbody fixation L5-S1, bone graft, allograft with 2-day LOS and DME: Cybertech TESO - Reference #955368

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 06-01-09 DD Report from Dr.
- o 07-20-09 Chart Note from Dr.
- o 08-03-09 Lumbar MRI read by Dr.
- o 08-03-09 Chart Note from Dr.
- o 08-05-09 Request for preauthorization for surgery from Dr.
- o 09-09-09 Adverse determination letter
- o 09-17-09 Mental Health Evaluation from Dr.
- o 09-23-09 Acknowledgement of Request for Reconsideration letter
- o 09-29-09 Adverse determination letter for appeal
- o 10-09-09 Request for IRO from Dr.
- o 10-12-09 Confirmation of Receipt of IRO from TDI
- o 10-12-09 Notice of Case Assignment of IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a xx-year-old female employee who sustained an injury to the low back on xx/xx/xx.

The patient was examined by a Designated Doctor on June 1, 2009. Her injuries are consistent with the work injury as described. She reports low back pain that radiates into the left leg as far as the thigh with pins and needles sensations which inhibit her activities and sleep. She notes a pain level of 4/10 which can increase to 8/10 on occasions. Health conditions include asthma and high cholesterol. A lumbar MRI of March 10, 2008 reportedly reveals some degenerative changes as well as a distinct IVD injury in the L5-S1 level. Nerve studies performed on March 7, 2008 have shown objective evidence of a left-sided radiculopathy of the S1 nerve, which correlate with her subjective complaints and treatment history. She has undergone active and passive treatments without significant resolution of her condition. She has been provided two facet joint injections which provided some to minimal relief. She has undergone a rhizotomy. The patient is 5' 5" and 165 pounds. The patient has a diagnosis of lumbar IVD

disorder without myelopathy and lumbago.

The patient was reevaluated on July 20, 2009 by her provider. Imaging and interventions were reviewed: Caudal epidural injections were performed on April 28, 2009 and June 2, 2009 with 100% pain relief noted for 3 days with the initial injection and 6 days of good relief with the second injection. On August 15, 2008 Dicom plain films including flexion/extension views were taken and revealed 5 free lumbar vertebra in good alignment; disc space narrowing at L5-S1; facet hypertrophy L5-S1 bilaterally. On October 27, 2008 medial branch blocks were performed with good relief noted. The patient has undergone radiofrequency rhizolysis of the facet joints L4-5 and L5-S1 bilaterally on December 4, 2008. The patient attended 12 sessions of chiropractic/physiotherapy in 2008 as well as 10 sessions of a chronic pain management program. The patient reports the rhizotomy procedure of 8 months prior has provided 20% overall benefit. She reports persisting low back pain that radiates to the bilateral knees right greater than left. She continues to smoke 3 packs of cigarettes weekly despite being told repeatedly to stop. She does not use medication on a routine basis. She has access to ES Tylenol and Advil 800 mg. She can flex to 80 degrees but has difficulty returning to upright. Lateral bending reveals paraspinous spasms on the left. Extension and rotation is positive bilaterally, left greater than right with pain across the back. Reflexes are intact. Straight leg raise is negative. Motor strength is full. She reports numbness on the right from the mid-calf to the great toe along the L4 nerve root distribution. Recommendation was for repeat MRI.

Updated MRI was performed on August 3, 2009 and provided impression of: There is an asymmetric posterior disc bulge on the left at L5-S1 which appears to efface the exiting L5 nerve root. There is also disc desiccation with minimal annular bulges at L1-2 and L2-3. There is normal appearance to disc at L3-4 and L4-5.

The patient was reevaluated on August 3, 2009. The patient has reduced her smoking slightly to 2.5 packs weekly. She is using Tylenol ES 4-6 daily and alternating with OTC Ibuprofen 8-12 tablets daily. She is a candidate for ZUMA interbody fusion L5-S1 status post failed medial branch facet rhizotomies and persistent far lateral HNP into and through the foramen at L5-S1 on the left. Surgery was requested formally on August 5, 2009.

Request for anterior lumbar fusion L5-S1 with instrumentation was not certified in review on September 9, 2009 with rationale that there was no documentation of evidence of instability via flexion/extension films and a psychological assessment had not been reported.

A Mental Health Evaluation dated September 17, 2009 was subsequently submitted. The report indicates the patient does not have any psychological barriers to proceed with a surgery. She has a positive attitude and strongly desires to return to work.

Request for appeal lumbar surgery with fusion and instrumentation at L5-S1 was considered in review on September 28, 2009 with recommendation given for non-certification with rationale that, while the patient may be a candidate for decompression a fusion procedure is not warranted per guideline criteria. ODG states fusion can be considered when there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction or spinal fracture, dislocation, spondylolisthesis or frank neurogenic compromise, conditions not documented for this patient.

A request has been made for an IRO.

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

The patient reports persisting low back pain that radiates to the bilateral knees right greater than left. Imaging has shown an asymmetric posterior disc bulge on the left at L5-S1 which appears to efface the exiting L5 nerve root. The patient has left-sided S1 radiculopathy per nerve studies. Examination is significant for numbness on the right from the mid-calf to the great toe along the L4 nerve root distribution.

Plain films including flexion/extension views were taken and have shown 5 free lumbar vertebra in good alignment, disc space narrowing at L5-S1 and facet hypertrophy L5-S1 bilaterally. The patient has responded positively to facet injections and has positive provocative facet maneuvers.

The Official Disability Guidelines criteria for lumbar fusion allow this procedure when there is documentation of segmental instability (objectively demonstrable), excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment or 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. The data show that patients with back pain are more often rendered worse off by fusion surgery.

The patient may be a candidate for decompression. However, the clinical findings do not document the required criteria to warrant a fusion procedure. It is also noted that the patient would be at high risk for non-union as a heavy smoker and XX-year-old female. Recommendation is to agree with the previous non-certification for anterior interbody fusion L5-S1, anterior interbody fixation L5-S1, bone graft, allograft with 2-day LOS and use of Cybertech TESI.

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 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

The Official Disability Guidelines - Lumbar Chapter, (10-12-2009) Lumbar 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.

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. 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. 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) 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. (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.) 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.

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 - Spondylytic 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 disectomy. [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)