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DATE OF REVIEW: 06/30/2009

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

Decompression Laminectomy revision/fusion lumbar at L3, bilateral lateral fusion L3-4, posterior spinal fixation L3-4, removal of posterior fixation L4-5 bone allograft.

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 01-16-09 MRI lumbar spine read by Dr.
- o 02-19-09 Evaluation report from Dr.
- o 02-24-09 Medical Note from Dr.
- o 03-05-09 Lumbar CT scan report read by Dr.
- o 03-12-09 Evaluation report from Dr.
- o 04-13-09 Evaluation report from Dr.
- o 04-16-09 Evaluation report from Dr.
- o 04-22-09 Spinal surgery consultation report from Dr.
- o 05-15-09 Notification of Adverse Determination from Coventry
- o 05-28-09 Evaluation report from Dr. Dr.
- o 06-16-09 Notification of Reconsideration Determination from
- o 06-17-09 Request for IRO

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a employee who sustained an industrial injury to the low back when he fell 3 feet in a trench. The medical records indicate he is status post 3 lumbar surgeries (L4-5 discectomy 1991; L4-5 fusion 1997; L3-4 decompression September 2008).

Lumbar MRI performed January 16, 2009 shows post-operative changes in the lower lumbar spine with L4-5 vertebral fusion and intervening laminectomies. Multilevel lumbar spondylotic changes. There is moderate bilateral foraminal narrowing at L3-4 and L4-5. There is no spinal canal stenosis at any level. No evidence of discreet fracture or abscess.

The patient reported severe back pain at follow-up on February 19, 2009. He did well for several months following his most recent surgery but more recently feels he is regressing to pre-surgery pain levels. CT myelogram is recommended. He may need pain management or a dorsal column stimulator, if there are no significant findings on myelogram.

On February 24, 2009 the patient called his provider and reported RME evaluation orthopedic testing aggravated his back pain. He reported muscle spasms and falling as he left the examination area and then again upon arriving at home. Myelogram of March 5, 2009 showed no spondylolisthesis. L4 and L5 have bilateral pedicle screws with an intervening fusion basket. There are no compression fractures. The disc spaces are well maintained in height. The conus medullaris lies posterior to L1 and is normal. Impression states, moderate spinal canal and moderate left neural foraminal stenosis at L3-4. Removal of spinous processes of L3, L4 and L5. Bilateral pedicle screws and intervening fusion basket at L4-5.

On March 12, 2009 the provider interprets the myelogram to show recurrent spinal stenosis at the L3-4 level which undoubtedly traps the scar tissue between the dura and the lamina. Recommendation is for surgical revision of the laminectomy, extending the laminectomy defect very wide taking out most of the facet joints. This would require extending the fusion to the L3 level. This would also require removal of the current instrumentation as the instrumentation is outdated and no longer made.

The patient was provided a pain management consultation on April 13, 2009 indicates the patient has a high pain level which is always present. He has previously had epidural injections, trigger point injections and PT. He does not smoke. Medications include Singulair, Protonix, Lyrica, Cymbalta, Dilaudid, clonazepam, Lipitor and Lorezepam. Straight leg raise is positive at L3-4 and L4-5 bilaterally, more so to the left. There is diminished sensation and strength of 4/5. He will initiate Kadian 30 mg twice daily.

A second surgical opinion was provided on April 22, 2009. He has recently developed buttock and right leg pain. CT myelogram has shown some stenosis and breakdown at the level of the previous fusion. He is 5' 10" and 210 pounds. There is some decreased sensation in the right L5 distribution. Otherwise he is neurologically intact. There is some right dorsiflexion weakness of the foot. Straight leg raise reproduces L5 radiculopathy on the right. He does exhibit some signs of symptom magnification. Recommendation is for decompression and extension of fusion to the L3 level with aggressive postoperative physical therapy.

Request for decompression laminectomy revision/fusion was not certified in review on May 15, 2009 following an attempted peer discussion with rationale that it appears that clinical findings relate to the L5 level. The patient reportedly attended an RME however the evaluation report has not been made available for review. Additionally, the records contain no evidence of a pre surgical psychological evaluation despite symptoms of symptom magnification.

The provider responded with submission of an updated progress report dated May 28, 2009. The patient reports increased low back pain and a feeling of instability with several falls since twisting his back while hanging a picture. On examination there is weakness in the right EHL of 0/5, 2/5 strength in the tibialis anterior and 3/5 strength in the peroneal musculature. Quadriceps and hamstring musculature strength is 4/5 on the right. Sensation is intact but markedly decreased on the right as compared to the left. Straight leg raise is positive on the right at 5 degrees. Radiographs were taken and show some degeneration at L1-2 and narrowing at the L3 disc on top of his L4-5 fusion. Recommendation is for EMG/NCV of the bilateral lower extremities. He needs decompression of the L3-4 level as the bone has grown across the spinal canal at this level. This is clearly seen in the clear demarcation between the cut portion of the lamina and the new bone growth. If denied, we will proceed with his private insurance. He did spend 3 days in the hospital earlier this year.

Request for reconsideration for decompression laminectomy revision/fusion was not certified in review followed an attempted peer discussion on June 16, 2009 with rationale that the requested electrodiagnostic studies were not made available for review to clarify if the patient's symptoms correlate with the diagnostic findings. The physician has documented that the patient has instability but the report identifying this is not included in the records. It is not clear that all pain generators have been identified. There is also no psychological evaluation and this would be most important as the medical records document a history of anxiety and depression and that the claimant is on narcotic medication. Lastly the patient's smoking history is unclear.

Request was made for an IRO.

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

The patient is status post three lumbar surgeries and has imaging findings of moderate bilateral foraminal narrowing at L3-4 and L4-5 without spinal canal stenosis seen at any level. Pain management or a dorsal column stimulator was recommended if myelogram results were benign. Myelogram showed moderate spinal canal and moderate left neural foraminal stenosis at L3-4, findings which are mildly significant. The provider interprets the CT myelogram as, showing recurrent spinal stenosis at the L3-4 level which undoubtedly traps the scar tissue between the dura and the lamina. Recommendation is for surgical revision of the laminectomy, extending the laminectomy defect very wide taking out most of the facet joints and extending the fusion to the L3 level. The pain management consultation of April 13, 2009 clarifies that the patient does not smoke. Per a second surgical opinion, there is some decreased sensation in the right L5 distribution, otherwise he is neurologically intact. There is some right dorsiflexion weakness of the foot. Straight leg raise reproduces L5 radiculopathy on the right. He does exhibit some signs of symptom magnification.

A prior review noted clinical signs indicate L5 radiculopathy. There do not appear to be clinical signs correlating with imaging findings of moderate spinal canal and moderate left neural foraminal stenosis at L3-4. More recently, the patient has an

exacerbation and right-sided clinical findings are reported with weakness in the right EHL of 0/5, 2/5 strength in the tibialis anterior and 3/5 strength in the peroneal musculature noted. Quadriceps and hamstring musculature strength is 4/5 on the right. Again, with exception of the quadriceps muscle weakness, these appear to be deficits associated primarily with the L5 dermatome. The patellar reflex (L4) was not tested. As noted prior the RME report and electrodiagnostic studies are not available for review and a psychological assessment does not appear to have been completed. It is not clear that a surgery focused on L3-4 will resolve the patient's pain. At this time, the medical records fail to document a medical necessity to proceed with the requested intervention. Therefore, my recommendation is to agree with the prior non-determination for decompression laminectomy revision/fusion lumbar at L3, bilateral lateral fusion L3-4, posterior spinal fixation L3-4, removal of posterior fixation L4-5 bone allograft.

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 - Low Back (6-25-2009), Spinal 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)]

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.

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) 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) 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.

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 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)