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An Independent Review Organization
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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Dec/15/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L3/4, L4/5, L5/S1 ALIF Posterior Decompression, L2/S1 with B Foraminotomies, Pedicle Screw Fixation L2/S1, Harvesting OPICBG Posterolateral fusion utilizing transverse process technique 2-3 day LOS with bone stimulator

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

Peer Reviews 10/22/08, 11/11/08

MRI lumbar spine, 05/16/07

MRI flexion / extension, 06/16/07

EMG/NCS lower extremity, 12/07/07

X-ray lumbar spine, 05/28/08

Lumbar discogram, 10/03/08

Office notes, Dr. , 05/30/07, 05/28/08, 06/30/08, 09/19/08, 10/20/08

Letters from Dr. , 07/24/08, 11/10/08

Dr. / DDE, 10/10/08

Dr letter, 11/10/08

Procedure, 07/05/07

Psychological evaluation, 09/04/08

Correspondence, 11/26/08, 12/09/08

PATIENT CLINICAL HISTORY SUMMARY

This is a xx year-old male claimant who reportedly had low back pain on xx/xx/xx after lifting a water heater. The records indicated that the claimant has been diagnosed with lumbar segmental instability with multilevel internal disc derangement and has remained out of work since the reported injury. A physician record dated 05/30/07 noted the claimant with left sided low back pain and left lower extremity discomfort. Conservative treatment had consisted of physical therapy and medication. A review of a lumbar MRI done on 05/16/07 showed multilevel posterior annular tears, L2-3, L3-4 and L4-5 with a left sided L4-5 disc herniation resulting in moderate to severe spinal canal stenosis and impinging on the left L5 nerve root. A left L5- S1 epidural steroid injection was recommended and performed on 07/05/07. An EMG/ NCS followed on 12/07/07 which showed strong evidence for severe left sided L5 and S1 radiculopathies.

A physician evaluation of 05/28/08 noted the claimant with lower extremity pain greater than low back pain. It was noted that the epidural steroid injections had provided several days of relief and then the leg pain returned. The claimant had undergone therapy and was taking Flexeril occasionally. On examination, motor weakness was noted in the left lower extremity along with a decreased sensibility to light touch in the left lower extremity L5 and S1 distributions. The claimant was diagnosed with L4- 5 and L5- S1 left subarticular disc herniations resulting in left L5 and S1 nerve root compression, moderate to severe left lower extremity motor weakness, left L5 and S1 radiculopathy and L2-3 and L3-4 mild central canal stenosis secondary to a large broad based disc herniation. X-rays taken showed a mild retrolisthesis of L4 and L5 and L3 on L4 with mildly diminished disc space.

Follow up physician records in June 2008 noted the claimant with continued low back and left lower extremity pain associated with a give way sensation of the left foot and ankle. It was determined that the claimant was a surgical candidate due to segmental instability and posterior disc herniations and radiculopathy. A psychological evaluation performed on 09/04/08 noted the claimant appeared to be a good surgical candidate. A lumbar discogram followed on 10/03/08 which revealed concordant pain at the L3-4, L4-5 and L5-S1 levels.

A Designated Doctor Examination was performed on 10/10/08 which noted the claimant with continued lower back pain and left leg pain. It was determined that the claimant had not reached maximum medical improvement. A follow up treating physician visit dated 10/20/08 noted the claimant with lumbar instability, multilevel disc herniations with progressive lower extremity weakness and radiculopathy. Surgery was recommended in the form of an anterior lumbar interbody fusion L3-4, L4-5, and L5- S1 for disc derangement and discogenic pain, posterior decompression L2-3, L3-4, L4-5 and L5- S1 with bilateral foraminotomies in addition to pedicle screw fixation L2-3, L3-4, L4-5 and L5-S1 to include harvesting of iliac crest bone graft and posterolateral fusion utilizing transverse process technique with both allograft as well as autograft.

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

The medical records in this case would confirm electrodiagnostic evidence of radiculopathy. There are MRI findings to correspond to physical findings and electrodiagnostic findings. The discographic findings were positive over the proposed levels with a negative control level. The psychologic screening evaluation was not concerning. Both the Designated Doctor Evaluation examiner and the treating physician have documented neurologic deficits.

When one turns to closed to the Official Disability Guideline criteria it would certainly appear that a thorough evaluation for pain generators has been conducted. It would appear that conservative care, including physical therapy and epidural steroids have failed. The MRI and discographic study provides evidence of disc pathology which correlated with the physical examinations and with the electrodiagnostic tests. It cannot be helped that the pathology is not limited to two levels and this is not a disqualifying criterion. Psychosocial screening is unremarkable. There is no documentation of an active smoking history. In short, when one applies these records strictly to the Official Disability Guidelines, the Reviewer's assessment

is that this claimant would be a candidate for the procedure. Based on the Official Disability Guidelines, the Reviewer would recommend this medically necessary the proposed procedure. The Milliman Guidelines would approve up to a three day length of stay. A bone growth stimulator would be appropriate due to the multilevel fusion procedure.

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates, Low Back. Fusion 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 unilateral neural arch hypoplasia.
- (2) Segmental Instability - 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
- (3) Primary Mechanical Back Pain/Functional Spinal Unit Failure, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability, with and without neurogenic compromise. 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.
- (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

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion 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-ray demonstrating spinal instability and/or MRI, Myelogram or CT discography 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.

Low Back: Bone growth stimulators (BGS)

Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high risk cases). Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated.)

Criteria for use for invasive or non-invasive electrical bone growth stimulators

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion: (1) One or more previous failed spinal fusion(s); (2) Grade III or worse spondylolisthesis; (3) Fusion to be performed at more than one level; (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a

risk factor); (5) Diabetes, Renal disease, Alcoholism; or (6) Significant osteoporosis which has been demonstrated on radiographs.

Milliman Care Guidelines. Inpatient and Surgical Care 12th Edition

Lumbar fusion: Goal Length of Stay: 3 days postoperative:

Extended Stay: Extensive, multilevel, or combined (anterior and posterior) procedures Other procedures may be necessary, particularly with extensive blood loss. Expect brief stay extension.

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

ACOEM-AMERICA 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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)