



IRO REPORT

DATE OF REVIEW: 6/4/07

IRO CASE #:

NAME:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Determine the appropriateness of the previously denied request for explantation of transpedicular fixation device with re-exploration of fusion (2 levels) L4-L5 and L5-S1.

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

Texas Licensed

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)

The previously denied request for explantation of transpedicular fixation device with re-exploration of fusion (two levels) L4-L5 and L5-S1.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- Fax Cover Sheet/Note/Authorization Request dated 6/1/07, 5/16/07, 4/20/07, 5 pages.
- Confirmation of Receipt of a Request for a Review by an Independent Review Organization (IRO) and Fax Transmittal dated 5/31/07, 2 pages.
- Notice to CompPartners, Inc. of Case Assignment dated 6/1/07, 1 page.
- Notice to Utilization Review Agent of Assignment of Independent Review Organization dated 6/1/07, 1 page.

- **Company Request for Independent Review Organization dated 5/31/07, 4 pages.**
- **Request for a Review by an Independent Review Organization dated 5/31/07, 3 pages.**
- **Determination Notification Letter dated 5/22/07, 4/25/07, 5 pages.**
- **Follow-Up Visit Report dated 2/8/07, 2 pages.**
- **Lumbar Spine Myelogram Report dated 2/21/07, 1 page.**
- **Lumbar Spine CT dated 2/21/07, 2 pages.**
- **Demographics Sheet dated 4/18/07, 1 page.**
- **Lumbar Spine MRI dated 2/8/07.**
- **Request Letter for Reconsideration dated 5/8/07, 1 page.**
- **Workman's Compensation Pre-Authorization Form (unspecified date), 1 page.**

PATIENT CLINICAL HISTORY [SUMMARY]:

Age:

Gender: Male

Date of Injury:

Mechanism of Injury: Not provided for review.

Diagnosis: Status post L4-S1 fusion with instrumentation, 7/4/01.

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

The 2/8/07 follow-up note indicated the patient continuing to have low back pain specifically radiating into the left leg. There were continued problems with control of urinary bladder. The pain was noted to be 7/10 in a scale of 1-10, 10 as being the worst. There was continued weakness left leg and foot. It was noted the patient had surgery in xxxx and had a subsequent footdrop on the left. The patient had regained some strength on left foot but still had continued problems ambulating. The physical examination revealed paravertebral muscle spasm, pain on palpation of her buttocks, range of motion noting flexion 45 degrees, extension 15 degrees, and lateral bending and rotation not carried out due to pain and guarding. Deep tendon reflexes were bilaterally present at the patella but absent at the Achilles. There was decreased sensation of the left leg compared to right but not indicated as dermatomal. Left extensor hallucis longus weakness was noted. There was positive straight leg raising on the left at 70 degrees causing increased back pain. The 8/14/06 MRI was reviewed indicating hypertrophic changes bilaterally at L3-4 mild narrowing of the lateral recess without significant spinal stenosis noted, and degenerative changes at L2-L3 were noted as well. The electromyogram (EMG) of 5/8/06 revealed irritability of the L3 through S1 motor roots with power reductions bilaterally with the left leg being much more symptomatic. There was absent right and left peroneal F waves and right and left tibial H. reflexes were indicative of a significant L5 and S1 radiculopathy on a residual basis, and also involvement of lower sacral S2 through S4 motor roots consistent with lower motor dysfunction associated with bladder and sexual abnormalities. The CT of 5/8/06 indicated loosening of the sacral screw and a question of the fusion at L4-5. The CT report reviewed did not indicate there being a question of

fusion at L4-5. On MRI, there was a soft tissue mass anterior to the thecal sac at both L4-5 and L5-S1, which could not be specified. The lumbar myelogram performed on 2/21/07 indicated post-operative changes at L4-5 and L5-S1 with interpedicular screws and interconnecting bars with cages in good position. There was a minimal impression on the anterior portion thecal sac at L2-3 and a little bit more at L3-4. There was underfilling of the nerve root sleeves at L3-4 bilaterally. The post myelogram CT indicated borderline or mild central spinal canal stenosis at L2-3, mild to moderate central spinal canal stenosis at L3-4 with some facet joint arthropathy and hypertrophy of the ligamentum flavum, post-operative changes at L4-5 with interpedicular screws and bone graft in good position, and interpedicular screws bone graft in good position at the L5-S1. There was no indication in that report of a pseudarthrosis or impending pseudarthrosis. In his letter of reconsideration, Dr. indicated that the patient, after the original surgery, had a significant amount of pain coupled with urinary incontinence and continued numbness and tingling in the left leg with the drop foot. Dr. reiterated his findings of positive straight leg raise at 60 degrees on the left, positive tension sign, and great difficulty carrying out range of motion due to guarding. Dr. indicated that there was loosening of the screws of the sacrum at L5 and probably L4. He wished to remove the hardware, enhance the status of the fusion with augmentation laterally, and foraminal decompression posteriorly at both levels based on the EMG. The electrodiagnostic study indicated diffuse changes at multiple levels, not just two. The medical records did not indicate findings of instability or pseudarthrosis that would indicate the need for augmentation of the fusion. The rationale for upholding the previous denial of the hardware removal is that modification to approve only part of the surgery is not allowed, but with the signs of loosening on imaging studies which indicate a probable pain generator and hardware removal, which has been recommended by the FDA, this would be an appropriate stand-alone request. The rationale for upholding the previous denial of the fusion augmentation is that the medical records do not indicate an instability, nor did the imaging studies indicate a pseudarthrosis both of which would be indicators for the augmentation of the fusion. The NEJM 350; 7, February 12, 2004 page 723 deal with the fundamental problem of plates in spinal fusions, including the lack of definitive methods to confirm a solid fusion, weak association between solid fusion and pain relief, and the placebo effect of surgery for pain relief. Although a solid fusion is somewhat more likely to result in pain relief, in fusion that are not solid (pseudarthrosis), many patients with the latter have excellent pain relief, while many who have a solid fusion get poor results. Furthermore, psychosocial factors are important predictors of the clinical outcome. Therefore, with no note of instability, diffuse electrodiagnostic study changes, imaging studies negative for pseudarthrosis or specific pain generator localized, the fusion is not indicated. However, if at the time of the hardware removal an absolute pseudarthrosis is found, then the augmentation of the fusion would be appropriate.

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 AND 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).

- NEJM 350; 7, February 12, 2004 FDA recommendation

CompPartners, Inc. hereby certifies that the reviewing physician or provider has certified that no known conflicts of interest exist between that provider and the injured employee, the injured employee’s employer, the injured employee’s insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for the decision before the referral to CompPartners, Inc.
