

# P&S Network, Inc.

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## Notice of Independent Review Decision

### MEDICAL RECORD REVIEW:

**DATE OF REVIEW:** 07/22/2010 AMENDED: 7/22/2010

**IRO CASE #:**

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

This case was reviewed by an Orthopaedic Surgeon, 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**

Repeat Lumbar Laminectomy w/ L5-S1 Fusion (Aspen Procedure) with 1-day stay hospital

**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 03-04-10 Lumbar MRI read by Dr.
- o 03-11-10 Progress Notes from Dr.
- o 04-29-10 Progress Notes from Dr.
- o 05-12-10 History and Physical Examination from Dr.
- o 05-24-10 Progress Notes from Dr.
- o 05-27-10 Fax Pre-Certification request from Dr.
- o 06-01-10 Fax Pre-Certification request from Dr.
- o 06-04-10 Adverse Determination letter from
- o 06-08-10 Letter of appeal from Dr.
- o 06-10-10 X-Ray Report, lumbar, read by Dr.
- o 06-14-10 Fax Pre-Certification request for appeal from Dr.
- o 06-14-10 Appeal to denied preauthorization from Dr.
- o 06-22-10 Reconsideration - Adverse Determination letter from
- o 07-01-10 Request for IRO from the Claimant
- o 07-02-10 Confirmation of Receipt of Request for IRO from
- o 07-05-10 Notice to P&S of Case Assignment from

**PATIENT CLINICAL HISTORY [SUMMARY]:**

According to the medical records and prior reviews the patient is male who sustained an injury to the low back on xx/xx/xxxx when moving a heavy rack. He is status post L5-S1 lumbar hemilaminectomy on October 31, 2009.

Lumbar MRI performed March 4, 2009 was given impression: Recurrent left central disc herniation protrusion at L5-S1 producing displacement of the left S1 nerve root and left lateral recess stenosis. Evidence of left hemilaminectomy with facet arthropathy with lateral recess stenosis.

The patient was reevaluated on March 11, 2010. The MRI shows spondylitic changes at L5-S1. His spondylosis remains about the same. There is definite compression of the nerve on S1. He has positive straight leg raise on the left with radicular pain to the left lower extremity. He will be treated conservatively. Recommendation is for a brace, additional PT and chronic pain management.

The patient was reevaluated on April 29, 2010. He reports a pain level of 8/10. He was given prescriptions for topical Ketoprofen, Tramadol and Valium. He will have a second neurosurgical opinion per request of the carrier.

The patient was provided a neurosurgical consultation on May 12, 2010 for low back pain that travels to his left leg and down to the toes. He reports constant pain. He is using Tramadol, Valium and Ketoprofen cream. He has been treated with medications, pain injections and PT. He underwent nerve studies in October 2007. CT scan performed May 29, 2008 revealed an L5-S1 disc bulge compressing the S1 nerve root. He had a lumbar hemilaminectomy on October 31, 2009. He has been advised to have another surgery by his provider. He is to begin PT on May 17, 2010. He describes a burning sensation into the left leg and pins and needles sensations into his toes. Walking causes cramping in the left leg. He has difficulty with ADLs. He uses a motorized shopping cart when shopping. He is unable to work. He brings his recent lumbar MRI results. He smokes cigarettes. The examination states, "Complete Neurological Exam performed. The positive findings on examination, Spine inspection: healed scar. Palpation: produce pain. Range of motion is limited in lumbar. Gait: able to walk tip toe and heels with some difficulty. Lasegue: positive left. Sciatic Notch: positive left. Paravertebral muscle tone: increased. Motor weakness, Sensory pinprick produce pain, Vibration: intact." Diagnosis is recurrent disc herniation protrusion at L5-S1, lumbar radiculopathy and pain in the left lower extremity. "A second surgery for recurrent herniation at L5-S1 is recommended and could be beneficial." He will need medical clearance. He is referred back to his surgeon.

The patient was reevaluated by his provider on May 24, 2010. Left leg sensation is decreased in the S1 distribution. The neurosurgeon has recommended he should undergo "lumbar laminectomy and discectomy and fusion; an Aspen type redo laminectomy." He has "an unstable lumbosacral spine" with spondylolysis at the level of L5-S1 and fusion would be beneficial.

The provider submitted a letter of appeal dated June 8, 2010. The patient has grade I spondylosis at L5-S1. His examination has essentially remained the same. He has radicular pain going down the left lower extremity. He has been recommended to have lumbar spine fusion by the outside examiner. This has not been authorized in review. Recommendation was made for flexion and extension x-rays to see whether there is any instability. In my opinion this x-ray is useless. We will do the radiographs. However, what the patient needs is a lumbar laminectomy redo and fusion for spondylosis grade I spondylo and narrowing of the inner space.

Lumbar radiographs taken June 10, 2010 were given impression: Possible muscle spasm. Clinical correlation is suggested. No lumbar instability. Findings note, vertebral body height and alignment of L1-5 are maintained. No significant listhesis is seen with flexion and extension. Disc heights are normal. The possibility of L5 spondylolysis is raised.

Request for lumbar laminectomy re-do at L5-S1 with fusion was considered in review on June 4, 2010 with recommendation for non-certification. On March 11, 2010 the provider stated that the MRI showed spondylitic changes at L5-S1 and definite compression of the nerve at that level. On May 12, 2010 a consulting provider recommended surgery for a recurrent herniation at L5-S1. On May 24, 2010 examination showed positive left straight leg raise and decreased sensation in the left leg. Recommendation was for redo laminectomy at L5-S1 and fusion. The claimant has been treated with bracing, PT and chronic pain management. A peer discussion was realized. There has been no flexion/extension radiographs to substantiate a dynamic instability at L5-S1 of an MRI which demonstrated Grade I spondylolisthesis. The spondylolisthesis was known to the prior surgeon who did not think it was dynamic or needed addressing. Now there is evidence of a recurrent herniation. The patient has abnormal neurologic function and has failed appropriate conservative treatment. It is unclear why a fusion is needed for a recurrent herniation. There is no mention that the dissection would have to go out laterally to cause destabilization. There is also no mention why there was intrinsic instability of this or why this was not addressed in the initial operation. Flexion/extension radiographs may be helpful to delineate the true indication for the procedure that would need to be performed in this revision setting. Because an adverse determination for surgery has been rendered, an adverse determination for any associated pre-operative clearance is also rendered.

Request for reconsideration lumbar laminectomy re-do at L5-S1 with fusion was considered in review on June 22, 2010 with recommendation for non-certification. A peer discussion was attempted but not realized. The summary is similar to the initial review. Rationale for denial states, the patient injured his low back in August 2007 and underwent L5-S1 lumbar hemilaminectomy on October 31, 2009. MRI showed post-op changes with recurrent left central disc herniation protrusion at L5-S1, producing displacement of the left S1 nerve root and left lateral stenosis. There is no detailed neurologic examination with evidence of motor or sensory deficit in a specific myotomal or dermatomal distribution. Radiographs with flexion and extension views were performed on June 10, 2010 and reported possible muscle spasm, with no lumbar instability. ODG provides that after two failed discectomies fusion may be considered an option at the time of the third discectomy; however, this patient has had only one prior surgery. A presurgical psychological evaluation is also not documented.

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 disectomy. 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.

Per ODG, the 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.

First-line review denial rationale noted, lack of flexion/extension radiographs to substantiate a dynamic instability at L5-S1 of an MRI which demonstrated Grade I spondylolisthesis. The spondylolisthesis was known to the prior surgeon who did not think it was dynamic or needed addressing. It is unclear why a fusion is needed for a recurrent herniation. There is no mention that the dissection would have to go out laterally to cause destabilization. There is also no mention why there was intrinsic instability of this or why this was not addressed in the initial operation. Flexion/extension radiographs may be helpful to delineate the true indication for the procedure that would need to be performed in this revision setting.

Second-line review denial rationale notes lack of a detailed neurologic examination with evidence of motor or sensory deficit in a specific myotomal or dermatomal distribution. Radiographs with flexion and extension views were performed on June 10, 2010 and revealed possible muscle spasm, with no lumbar instability. ODG provides that after two failed discectomies fusion may be considered an option at the time of the third discectomy; however, this patient has had only one prior surgery. A presurgical psychological evaluation is also not documented.

The patient has clinical and imaging findings corroborative of recurrent left central disc herniation with neurocompression on the left S1 nerve root. He has exhausted conservative treatments. He is indicated for a redo surgery to relieve the pressure at left S1. Per second neurosurgical opinion, "a second surgery for recurrent herniation at L5-S1 is recommended and could be beneficial." There is not found a recommendation for a fusion procedure. Lumbar radiographs taken June 10, 2010 reveal no lumbar instability, well maintained vertebral body heights, good alignment of L1-5, and no significant listhesis seen with flexion and extension. ODG does not support a fusion procedure for this patient as there is no documentation of significant segmental instability at L5-S1, nor would instability be rendered with a simple decompression. The criteria for a fusion procedure have not been met. Additionally, a psychosocial screening has not been reported and the patient's smoking habit has not been addressed (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.)

Therefore, my recommendation is to agree with the previous non-certification for repeat Lumbar Laminectomy w/ L5-S1 Fusion (Aspen Procedure) with 1-day stay hospital

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 (2010) 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.

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. 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. Unilateral instrumentation used for the treatment of degenerative lumbar spondylolisthesis is as effective as bilateral instrumentation. 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. 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.

#### 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 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.