

CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: June 30, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Revision lumbar spine surgery with decompression, discectomy, and instrumented arthodesis from L3-S1 with evaluation of L2-L3 intraoperatively to repair both her stenosis, instability and discogenic pain with correction of her scoliosis/2 day inpatient stay/Implantable bone growth stimulator

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

This physician is a Board Certified Orthopedic Surgeon with over 13 years of experience.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who was injured on xx/xx/xx. She was walking upstairs and fell forward. While trying to stand up and balance herself, she fell backwards landing on her buttocks. Initial treatment included physical therapy and NSAIDS. She underwent 2 back surgeries, including lumbar microdiscectomy in 2009 and again in 2012. Additional treatment has included Trigger point injections and ESIs. According to the records, an MRI on June 15, 2011 showed disc protrusion L4-5 with bilateral lateral recess stenosis, bilateral neural foraminal narrowing and moderate to severe central spinal stenosis at that level.

On January 20, 2012, Procedure Note, Procedure: Lumbar Epidural Steroid Injection L4-5 Caudal approach.

On March 30, 2013, the claimant presented for follow-up post lumbar ESI. It was reported her pain decreased to her lower back up until them by 60 to 70%. Her pain was described as a pressure and tightness with radiating down her right leg with numbness that extends to her right knee and down her right ankle. On exam there was a loss of lumbar lordosis. There was tenderness over the surgical scar. Range of motion was limited with flexion at 20 degrees, extension of 10 degrees with pain radiating to the right lower extremity. Motor exam strength was 4/5. Sensory exam was consistent with dermatomal pattern consistent with L4-5.

ON March 6, 2014, MRI of the Lumbosacral Spine, Impression: L4-5 large disc herniation measuring 10 mm, which is significantly enlarged in comparison with previous MRI dated 6/15/11. L3-4 right paracentral disc herniation measuring 4 mm. L5-S1 disc herniation effacing the S1 nerve roots. Neural foramina stenosis. Facet arthropathy with facet effusions.

On April 29, 2014, the claimant presented for surgical consultation. She was ambulatory with an antalgic gait with a cane in her right hand. She had complaints of low back pain and leg pain, presenting bilaterally, although much worse on the right. X-rays including flexion-extension views revealed functional spinal unit collapse at L2-3, L3-4, L4-5 and L5-S1 with a scoliosis on AP view concave left, apex L3, standing lateral neutral film normal at L1-2 functional spinal unit measures 10 mm, L2-3 functional spinal unit measures 1mm, L3-4 functional spinal unit measures 5 mm, L4-5 functional spinal unit measures 1 mm, L5-S1 functional spinal unit measures 1 mm with laminotomy at L4-5 and L5-S1. L2-3, L3-4, L4-5 and L5-S1 meet clinical instability criteria for functional spinal unit collapse and ODG #2, #3, #5 lumbar spine fusion selection patients. On physical examination, lumbar spine positive spring test, interiliac crest line, positive extensor lag, positive sciatic notch tenderness bilaterally, although worse on the right, negative Fortin finger test. Positive flip test bilaterally, positive Lasegue's on the right at 45 degrees, contralateral positive straight leg raising on the left at 75 degrees, pain referred to back and right lower extremity, hypoactive knee jerk and ankle jerk on the right, absent posterior tibial tendon jerks bilaterally, paresthesias in the L4, L5, and S1 nerve root distribution on the right, weakness of gastroc-soleus, extensor hallucis longus, and tibialis anterior on the right without atrophy. Assessment: Failed lumbar spine syndrome with internal disc disruption syndrome, discogenic pain, stenosis, and instability with failure of conservative treatment. Plan: Two options, accept her disability and continue with conservative treatment or proceed with surgical intervention. Surgical intervention will be revision lumbar spine surgery with decompression, discectomy, and instrumented arthrodesis from L3 to S1 with evaluation of L2-3 intraoperatively to repair her stenosis, instability, and discogenic pain with correction of her scoliosis. We will proceed through the scheduling requirements of her insurance carrier to include EMG/NCV repeat and psychological clearance report.

On May 13, 2014, UR. Rationale for Denial: The Guideline criteria have not been met. The claimant is noted with complaints of low back pain into both legs but primarily on the right, status post two failed lumbar surgeries. However, there is no documentation noting a recent trial/failure of non-operative treatment and there is no evidence of instability and/or a psychosocial screen. Furthermore, there is no documentation noting guideline-associated spinal instability on reference imaging. Therefore, this request is not indicated as medically necessary and reasonable at this time.

On May 21, 2014, UR. Rationale for Denial: The claimant has had several prior surgeries. There is persistent low back and leg pain. There is stenosis on imaging. The exam shows deficits consistent with failed back syndrome and radiculopathy. There was no psychological clearance as recommended by the evidence based guidelines. The claimant has had injections in the past. The AP recommended a repeat EMG and psychological clearance. In my discussion with the AP, it was noted that the EMG indicated chronic changes at L5-S1. It was further noted that the psychological clearance was done 2 years ago. It was also discussed that it would be prudent to update the clearance prior to proceeding with this extensive surgery. Therefore, the appeal request for revision lumbar spine surgery with decompression, discectomy, and instrumented arthrodesis from L3-S1 with evaluation of L2-3 intraoperatively is not medically necessary.

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

Revision lumbar spine surgery is not indicated at the present time.

The claimant complains of pain in the lower back with radiculopathy following two failed spinal procedures. She has multiple levels of disc disease. has recommended revision lumbar spine surgery with decompression, discectomy, and instrumented arthrodesis from L3-S1, with possible decompression L2-3.

The Official Disability Guidelines (ODG) supports spinal fusion in the setting of instability. All pain generators should be identified. The claimant should also undergo preoperative psychological screening.

has recommended that the claimant undergo an EMG/NC study and complete a psychological clearance. The EMG/NC is necessary to define the primary pain generator. The psychological clearance is particularly important when considering such an extensive surgery with a prolonged recovery period. The results of both evaluations should be reviewed in detail, before moving forward with surgery. Surgery is not recommended based on the records reviewed.

As surgery is not recommended, the 2 day inpatient hospital stay and implantable bone growth stimulator would also not be recommended.

Therefore, the request for revision lumbar spine surgery with decompression, discectomy, and instrumented arthrodesis from L3-S1 with evaluation of L2-L3

intraoperatively to repair both her stenosis, instability and discogenic pain with correction of her scoliosis/2 day inpatient stay/Implantable bone growth stimulator is denied at this time.

PER ODG:

ODG Indications for Surgery™ -- Discectomy/laminectomy --

Required symptoms/findings; imaging studies; & conservative treatments below:

I. Symptoms/Findings which confirm presence of radiculopathy. Objective findings on examination need to be present. Straight leg raising test, crossed straight leg raising and reflex exams should correlate with symptoms and imaging.

Findings require ONE of the following:

- A. L3 nerve root compression, requiring ONE of the following:
 - 1. Severe unilateral quadriceps weakness/mild atrophy
 - 2. Mild-to-moderate unilateral quadriceps weakness
 - 3. Unilateral hip/thigh/knee pain
- B. L4 nerve root compression, requiring ONE of the following:
 - 1. Severe unilateral quadriceps/anterior tibialis weakness/mild atrophy
 - 2. Mild-to-moderate unilateral quadriceps/anterior tibialis weakness
 - 3. Unilateral hip/thigh/knee/medial pain
- C. L5 nerve root compression, requiring ONE of the following:
 - 1. Severe unilateral foot/toe/dorsiflexor weakness/mild atrophy
 - 2. Mild-to-moderate foot/toe/dorsiflexor weakness
 - 3. Unilateral hip/lateral thigh/knee pain
- D. S1 nerve root compression, requiring ONE of the following:
 - 1. Severe unilateral foot/toe/plantar flexor/hamstring weakness/atrophy
 - 2. Moderate unilateral foot/toe/plantar flexor/hamstring weakness
 - 3. Unilateral buttock/posterior thigh/calf pain

(EMGs are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)

II. Imaging Studies, requiring ONE of the following, for concordance between radicular findings on radiologic evaluation and physical exam findings:

- A. Nerve root compression (L3, L4, L5, or S1)
- B. Lateral disc rupture
- C. Lateral recess stenosis

Diagnostic imaging modalities, requiring ONE of the following:

- 1. MR imaging
- 2. CT scanning
- 3. Myelography
- 4. CT myelography & X-Ray

III. Conservative Treatments, requiring ALL of the following:

- A. Activity modification (not bed rest) after patient education (>= 2 months)
- B. Drug therapy, requiring at least ONE of the following:
 - 1. NSAID drug therapy
 - 2. Other analgesic therapy
 - 3. Muscle relaxants
 - 4. Epidural Steroid Injection (ESI)
- C. Support provider referral, requiring at least ONE of the following (in order of priority):
 - 1. Physical therapy (teach home exercise/stretching)
 - 2. Manual therapy (chiropractor or massage therapist)
 - 3. Psychological screening that could affect surgical outcome
 - 4. Back school (Fisher, 2004)

For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

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 discectomy, with 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. Spinal instability criteria includes 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 correlated with symptoms and exam findings; & (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](#)) For average hospital LOS after criteria are met, see [Hospital length of stay \(LOS\)](#).

ODG hospital length of stay (LOS) guidelines:

Discectomy (*icd 80.51 - Excision of intervertebral disc*)

Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) \$26,219

Best practice target (no complications) -- *Outpatient*

Laminectomy (*icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root*)

Actual data -- median 2 days; mean 3.5 days (± 0.1); discharges 100,600; charges (mean) \$34,978

Best practice target (no complications) -- *1 day*

Note: About 6% of discharges paid by workers' compensation.

Lumbar Fusion, posterior (*icd 81.08 - Lumbar and lumbosacral fusion, posterior technique*)

Actual data -- median 3 days; mean 3.9 days (± 0.1); discharges 161,761; charges (mean) \$86,900

Best practice target (no complications) -- *3 days*

Note: About 15% of discharges paid by workers' compensation.

Lumbar Fusion, anterior (*icd 81.06 - Lumbar and lumbosacral fusion, anterior technique*)

Actual data -- median 3 days; mean 4.2 days (± 0.2); discharges 33,521; charges (mean) \$110,156

Best practice target (no complications) -- *3 days*

Lumbar Fusion, lateral (*icd 81.07 - Lumbar fusion, lateral transverse process technique*)

Actual data -- median 3 days; mean 3.8 days (± 0.2); discharges 15,125; charges (mean) \$89,088

Best practice target (no complications) -- *3 days*

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). ([Mooney, 1990](#)) ([Marks, 2000](#)) ([Akai, 2002](#)) ([Simmons, 2004](#)) 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. ([Resnick, 2005](#)) Also see [Fusion](#) for limited number of indications for spinal fusion surgery. See [Knee & Leg Chapter](#) for more information on use of Bone-growth stimulators for long bone fractures, where they are recommended for certain conditions.

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. ([Kucharzyk, 1999](#)) ([Rogozinski, 1996](#)) ([Hodges, 2003](#))

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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**