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Notice of Independent Review Decision

DATE: April 2, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Inpatient Lumbar Fusion at L1-L2 for 3 Days Length of Stay (LOS) and Purchase of Lumbar Brace

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

The reviewer is a neurological surgeon with over 16 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:

01/04/13, 01/23/13, 02/20/13: Office Visit
01/21/13: Lumbar Myelogram report interpreted
01/21/13: CT Lumbar Spine with Myelogram report
02/20/13: Rationale for Surgery
02/21/13: Preauthorization Request Sheet
02/25/13: Medical Conference Note
02/25/13: UR Peer Review Referral Report
02/26/13: UR performed
02/26/13: Request for Reconsideration
03/05/13: Medical Conference Note
03/05/13: UR Peer Review Referral Report
03/06/13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who injured his back while lifting while at work on xxxxxxx. He is status post L2-L5 fusions in the past. He had instrumentation removed in 2009. His last fusion was at L2-L3 performed in 2004.

01/04/13: The claimant was evaluated for chronic low back pain. It was noted that he had confirmed disc space narrowing, gas-vacuum phenomenon, and anterior and lateral spondylosis with endplate changes at L1-L2 on his last x-rays of 03/20/12. There was no motion at the levels of the fusion. He has had two ESIs. The first ESI was at L1-L2, which he states helped significantly. He had a caudal ESI on 07/18/08, which he states worked better. He was given a Medrol Dosepak on his last visit, which helped for approximately 2-3 weeks. He stated that his pain on 01/04/13 was as bad as ever. It was noted that he had developed symptoms of intermittent claudications with walking or standing to the point that he had to sit down. It was noted that he takes Neurontin, Volteran, and Tylenol No. 3 p.r.n. On examination, he continued to have chronic hypesthesia in the left L4 and L5 distribution. His left dorsiflexion weakness was rated 0/5 and 3+/5 on the right. He was developing bilateral iliopsoas weakness rated 4/5, a new finding. SLR positive bilaterally to 70 degrees producing ipsilateral low back pain. ROM of the lumbar spine revealed forward flexion of 60 degrees and extension 10 degrees. IMPRESSION: Chronic left foot drop and partial foot drop on the right. Myofascial pain syndrome with trigger points. Lumbar dysesthesias and possible early claudications. Residual lower back pain, status post removal of lumbar instrumentation in 2009. Status post L2-L3 fusion in 2004. Status post L3 to L5 fusions in the more distant past. Probable junctional syndrome at L1-L2 with disc space narrowing, gas-vacuum phenomenon, and anterior and lateral spondylosis with endplate changes. PLAN: as the patient's pain has become intractable and intolerable and he has been developing symptoms of iliopsoas weakness and intermittent claudications, we will order a lumbar myelogram with post-myelogram CT scan. Medications were refilled. Return appointment after his myelogram for review. The patient may be a candidate for an L1-L2 fusion.

01/21/13: Lumbar Myelogram report interpreted. FINDINGS: Please note the patient has transitional lumbosacral anatomy with six lumbar type vertebral vertebrae present. The lowest lumbar vertebral segments being designated as L6 vertebral body. Ventral epidural defect of mild degree at L1-L2. IMPRESSION: Successful lumbar myelogram. Please refer to post-myelogram CT scan of the lumbar spine for additional diagnostic information.

01/21/13: CT Lumbar Spine with Myelogram report interpreted. IMPRESSION: Transitional lumbosacral anatomy. Multilevel postoperative and degenerative spondylosis within the lumbar spine. Varying degrees of neural foraminal narrowing as well as extraforaminal narrowing as outlined above. FINDINGS: L1-L2: Mild broad-based disc bulge, mild bilateral facet arthropathy and ligamentum flavum hypertrophy with calcifications of the ligamentum flavum. No significant spinal stenosis. There is foraminal extension of the disc bulge on the right with mild-moderate right neural foraminal stenosis as seen on series 603, image 26.

01/23/13: The claimant was reevaluated. On examination, he stood with 10 degrees of lumbar flexion. He was unable to stand straight without developing pain in the low back and both legs. Motor exam revealed 0/5 left foot dorsiflexion weakness. There was 4/5 bilateral iliopsoas weakness. There was some slight

right foot dorsiflexion weakness. SLR bilaterally at 60 degrees produced low back pain. Sensory exam revealed hypesthesia to pin over the left shin and left foot. DIAGNOSTICS: Lumbar myelogram dated 01/21/13 is reviewed. AP views reveal a bar defect at L1-L2. Lateral views reveal a ventral and dorsal defect at L1-L2. Post-myelogram CT scan reveals L1 and L2 retrolisthesis. There is a diffuse L1-L2 disc protrusion. There is severe bilateral L1-L2 facet hypertrophy producing lumbar stenosis. IMPRESSION: Lumbar stenosis L1-L2 secondary to diffuse disc protrusion as well as facet and ligamentous hypertrophy. Transitional syndrome/junctional syndrome L1-L2. Status post L2-L3 fusion in 2004. Status post L3 to L5 fusions in the more distant past. RECOMMENDATIONS: The patient is very symptomatic from L1 and L2 lumbar stenosis. He has low back pain and bilateral leg pain and bilateral leg weakness with neurogenic claudications with symptoms increasing whenever he stands or walks more than 10 feet. The patient will need an L1-L2 decompression and fusion. We will obtain a preoperative psychological evaluation as per ODG with regards to lumbar fusion. We will see him back following this for review.

02/20/13: The claimant was reevaluated. He complained of bilateral lower extremity weakness, which had progressed. He was noted to have a left foot drop, "an old problem." It was noted that he had a psychological evaluation per who noted there were no psychological contraindications to the patient having spinal surgery. Physical exam remained unchanged from 01/23/13. RECOMMENDATIONS: The patient continues to be very symptomatic from L1 and L2 lumbar stenosis. He has developed a junctional syndrome/transitional syndrome at L1-L2 above his old fusion at L2-L3, which he had in 2004. He has developed bilateral iliopsoas weakness as well as some slight right foot dorsiflexion weakness. He has done well after his prior surgeries. He has now been symptomatic for two years with pain in the low back and both lower extremities. He has had extensive conservative treatment including two lumbar ESIs, which did not give him any long-term relief. Pain has gradually gotten worse over the last two years, and he has developed bilateral lower extremity weakness, which has progressed and he is having increased difficulty walking. He is unable to walk more than 10 feet. Any standing and walking greater than 10 feet produces increased pain in the low back and both legs as well as bilateral leg weakness and he has to sit down. He will need surgery at the L1-L2 level first to decompress the thecal sac and nerve roots and then to stabilize the L1 and L2 motion segment as he has a junctional/transitional syndrome and already has abnormal motion at this level with L1 and L2 retrolisthesis. He will need bilateral facetectomies to adequately decompress the spinal cord as well as a discectomy. This would render his spine unstable and he would have surgically induced segmental instability, thus necessitating a fusion in addition to a decompression. The patient meets all ODG as follows: He has been symptomatic for greater than six months. He has segmental instability (L1 and L2 retrolisthesis). He has functional spinal unit failure at L1-L2 with progressive degenerative changes, loss of disc height and loss of disc loading capability. All pain generators have been identified and treated. All physical medicine and manual therapy interventions have been completed and not been successful. Lumbar myelogram and post-myelogram CT scan revealed severe stenosis at L1-L2 with L1 and L2

retrolisthesis. Spine pathology is limited to the L1-L2 level. The patient has undergone a psychological screen on 02/13/13 with no contraindications to surgery. The patient does not smoke.

02/25/13: had a medical conference with. Mr. clinical situation was discussed. noted that the claimant had developed a junctional/transitional syndrome above an old L2-L3 fusion that was performed in 2004 and had L1 and L2 retrolisthesis with facet hypertrophy and bulging discs, all of which were producing some stenosis with a bar defect noted on the lumbar myelogram. It was noted that was going to send the actual films for review.

02/26/13: UR performed. RATIONALE: The documentation indicates the claimant had an injury on xxxxxx, xx years ago, when he was lifting and developed pain. There are no details of the original diagnosis and treatment. Although, the documentation indicates that the patient has continued having pain and developed a left foot drop and has had multiple fusions on the lower lumbar spine, posterior decompression and fusion L3-L5 with no dates and also L2-L3 decompression fusion in 2004. Recently, the claimant has had a CT scan and myelogram dated 01/21/13 that disclosed a bar defect at L1-L2 with DDD identified. In the multiple fusions between L3-L5, there are calcifications of the disc and in cogent at those levels. There is an L1-L2, L2-L3 disc bulge, but there are no stenoses identified by the radiologist. There is an x-ray that confirms multiple DDD at the L3-L5 levels with friction extensions showing no instability. There are MRIs of pelvis and hip that show bone marrow edema and hip joint arthritis BI. Surgery besides the fusion included a removal of the hardware on 11/24/09. The office notes from the treating physician are extremely limited, there is no clear comprehensive evaluations of the claimant's symptomatology showing subjective complaints of back pain, leg pain, hip pain and no detailed neurological or physical examination. Although, it says that there is BI leg weakness but very limited. There are no sufficient examinations to identify the pain generators or a clinical diagnosis. The claimant also had a psychological evaluation with no significant anxiety or depression that cannot be ignored. There is significant spinal L3-L4 PO calcified disc as well as L4-L5 that extended into the foramen, there is no indication of instability or stenosis at the L1-L2 and L2-L3 level to justify the requested surgery. This request does not follow the ODG guides which recommend a thorough physical and neurological examination as well as a comprehensive detailed exam of the claimant's objective and subjective symptoms. For this chronic pain lumbar syndrome secondary to failed back surgery, recommend having a comprehensive exam by specialist in multi-disciplinary clinics and attempt to treat the chronic pain syndrome with conservative management and proper clinical identification of the pain generators.

02/26/13: Request for Reconsideration. "Unfortunately, the surgery was denied by the reviewing physician. In his report, states that the patient has 'chronic pain lumbar syndrome secondary to failed back surgery.' I disagree with this statement. The patient does not have a failed back syndrome. While he has had prior lumbar spine surgery, he has improved after each and every low back surgery that he has had. Each of the surgeries have resolved his preoperative

symptoms, and the patient was able to work and function normally. He does not meet the criteria of a failed back syndrome as his surgeries were all successful with resolution of his symptoms after each one. Without surgery, his condition will decline and he will almost certainly become wheelchair bound.”

03/05/13: had a medical conference discussing the claimant’s need for lumbar decompression and fusion at L1-L2.

03/06/13: UR performed. RATIONALE: The injured worker is stated to have bilateral leg pain, but there are no physical findings to support a decompression. There may be claudication, but it is not well characterized. We do not know the level of the conus and have no record of his bladder control. We do not have a copy of the x-rays or MRI. The above ODG is for L3-L4 but would be similar for L1-L2 except for the level. It is stated that he meets the criteria for fusion that is not documented by x-ray reports. It is interesting that his pain is low back but the fusion suggested is L1-L2. It is also stated that he improved aft his prior surgeries and this may be a new problem. There is no documentation of level of improvement by pain medication usage, return to work, or documented other improvement in function. The disability from a total fusion of the lumbar spine is not detailed in the records for this patient and his activities. Therefore, the medical necessity of the requested procedure is not established.

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

The previous adverse determinations are upheld. After review of the claimant’s records, it appears that he has had progressive back pain and leg claudication symptoms for two years. His exam is noteworthy for bilateral hip flexor and right dorsiflexor weakness that are new also. He has an extensive back surgery history with that being approved by Workers’ Compensation in the past by all indications. His present radiographs suggest that there is degenerative disc disease at L1-L2 that has progressed and is associated with retrolisthesis, disc bulge, ligamentum flavum calcification, and some degree of stenosis centrally and foraminally. Although the radiologist does not rate the stenosis as significant, there is no discussion of where the conus ends, and sees the stenosis as contributing to the claimant’s neurologic symptoms.

According to ODG criteria, the claimant meets the standard of symptoms greater than six months. He also has what can be described as surgically-induced instability above his prior L2-L3 fusion with increased motion seen with retrolisthesis. Disc space collapse at L1-L2 also is consistent with segmental failure causing mechanical back pain. His prior surgical history suggests that he does get significant pain relief with surgery. So he appears to be a good candidate for this “revision” surgery. However, there is no documentation that movement at L1-L2 meets the 4.5 mm criteria statically or on flexion/extension views. The medical records sent for review did not indicate whether the claimant has undergone a trial of physical therapy for 4-6 weeks. There was also no documentation sent to review as to whether the claimant had an orthopedic evaluation done to rule out his hips as a pain generator/contributor to his gait

problems or whether his conus under is under pressure at the L1-L2 level suggesting some cord compression. Without documentation of the above, he does not fully meet ODG criteria.

The issue of bracing the claimant after surgery seems appropriate given his likely decreased bone density and the LOS of 3 days meets ODG criteria. However, as the request for Inpatient Lumbar Fusion at L1-L2 does not fully meet ODG criteria and therefore is found to be not medically necessary at this time, the request for 3 Days Length of Stay (LOS) and Purchase of Lumbar Brace would also not be medically necessary at this time.

ODG:

Fusion (spinal)	<p>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.)</p> <p>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)</p> <p>For average hospital LOS after criteria are met, see Hospital length of stay (LOS).</p>
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Discectomy/ laminectomy	<p>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:</p> <ul style="list-style-type: none"> A. L3 nerve root compression, requiring ONE of the following: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 <p>(EMGs are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)</p> <p>II. Imaging Studies, requiring ONE of the following, for concordance between radicular findings on radiologic evaluation and physical exam findings:</p> <ul style="list-style-type: none"> A. Nerve root compression (L3, L4, L5, or S1) B. Lateral disc rupture C. Lateral recess stenosis <p>Diagnostic imaging modalities, requiring ONE of the following:</p> <ul style="list-style-type: none"> 1. MR imaging 2. CT scanning 3. Myelography 4. CT myelography & X-Ray <p>III. Conservative Treatments, requiring ALL of the following:</p> <ul style="list-style-type: none"> A. Activity modification (not bed rest) after patient education (>= 2 months) B. Drug therapy, requiring at least ONE of the following: <ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> 1. Physical therapy (teach home exercise/stretching) 2. Manual therapy (chiropractor or massage therapist) 3. Psychological screening that could affect surgical outcome <p>4. Back school (Fisher, 2004)</p> <p>For average hospital LOS after criteria are met, see Hospital length of stay (LOS).</p>
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Hospital length of stay (LOS)	<p>ODG hospital length of stay (LOS) guidelines: Discectomy (<i>icd 80.51 - Excision of intervertebral disc</i>) Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) \$26,219 Best practice target (no complications) -- 1 day Laminectomy (<i>icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root</i>)</p>
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	<p>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 <i>Note: About 6% of discharges paid by workers' compensation.</i> 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 <i>Note: About 15% of discharges paid by workers' compensation.</i> 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</p>
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<p>Back brace, post operative (fusion)</p>	<p>Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease. Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable. (Resnick, 2005)</p>
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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)**