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DATE: September 14, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

2-day inpatient stay for an anterior lumbar interbody fusion at L4-L5 and L5-S1 with posterior lumbar decompression to include bilateral facetectomies thus predisposing the patient to iatrogenic instability, posterolateral fusion and pedicle screw instrumentation at L4-L5 and L5-S1

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

The reviewer is certified by the American Board of Neurological Surgery with over 23 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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who injured his back when performing lifting activities at work as a on XX/XX/XXXX. Records indicate that he underwent L4-L5 discectomy in the past.

02/26/14: A discharge summary, documents that the claimant had undergone 10 physical therapy sessions. It was noted that the services were no longer required due to the physician's request for discharge. He was educated regarding a home exercise program.

10/03/14: The claimant was evaluated for low back pain with radiation into the right lower extremity with numbness. His pain level was rated as 7/10. On exam, lumbar range of motion was restricted in forward flexion secondary to pain, and he exhibited difficulty returning to neutral position. Motor exam revealed 4/5 strength in the EHL, tibialis anterior, and gastrocnemius on the right; otherwise 5/5 throughout. DTRs were 1+ at the ankle on the right; otherwise 2+ throughout and symmetrical. Plantar responses were flexor bilaterally. Gait was antalgic. He had difficulty heel and toe walking secondary to pain. SLR was positive at 40 degrees, right greater than left. Sensory exam revealed a hypoesthetic region over the L5 and S1 distributions on the right to pinprick and light touch. Coordination was intact. Impression was recurrent lumbar radiculopathy, lumbar mechanical/discogenic pain syndrome at L4-L5 and L5-S1, recurrent herniated nucleus pulposus at L4-L5 and L5-S1, and lumbago status post remote surgical decompression. It was noted that he had evidence of L4-L5 disc herniation and ligamentum flavum hypertrophy contributing to right greater than left-sided foraminal stenosis and lateral recess stenosis as well as retrolisthesis of L5 on S1 of approximately 3-4 mm with disc herniation and annular tear. recommended ALIF at L4-L5

and L5-S1 with posterior lumbar decompression, posterolateral fusion, and pedicle screw instrumentation at L4-L5 and L5-S1.

10/20/14: The claimant was evaluated for low back pain. She recommended bilateral L4-L5 transforaminal epidural steroid injection vs caudal catheter as patient did have an L4-L5 discectomy in the past. She planned to refill hydrocodone 10/325 mg if necessary at next visit.

10/21/14: The claimant underwent presurgical behavioral health evaluation who cleared him for surgery from the behavioral health aspect.

10/22/14: Lumbar spine x-ray report. IMPRESSION: No significant interval change since 07/22/14. Suggestion of 1-2 mm retrolisthesis of L5 on S1 that appears stable on both flexion and extension. No compression fracture. Lower mid lumbar scoliosis with left convexity with the scoliosis Cobb's angle of approximately 3 degrees.

11/14/14: MRI lumbar spine report. IMPRESSION: Small solid enhancing hypervascular intramedullary mass in the conus medullaris at the level of T12 measuring 8 x 8 x 16 mm, likely either an ependymoma, astrocytoma, or metastasis. 2 mm right paracentral disc protrusion at L2-L3, which mildly impinges upon the thecal sac and mildly narrows the right lateral recess. 3 mm right foraminal disc protrusion at L3-L4, which moderately narrows the right foramen and contacts the inferior surface of the exiting right L3 nerve root. 4 mm posterior disc protrusion at L4-L5, which mildly impinges upon the thecal sac and moderately narrows the foramina and lateral recesses, worse on the right than the left. There is also a mild degree of degenerative facet and ligamentum flavum hypertrophy which contributes to canal, foraminal, and lateral recess narrowing. Grade 1 retrolisthesis at L5-S1 with a superimposed 5 mm right paracentral and foraminal disc protrusion at L5-S1, which mildly impinges upon the thecal sac and moderately narrows the right foramen and lateral recess. There is also mild degenerative facet and ligamentum flavum hypertrophy which contributes to foraminal narrowing. Mild degenerative facet joint hypertrophy at L3-L4, L4-L5, and L5-S1.

12/05/14: The claimant was evaluated for low back pain. He stated that he had no significant improvement in his prior symptomatology and described low back pain with radiation mainly into the right lower extremity with numbness. He rated his pain as 7/10. He reported losing bladder control on 11/14/14. He denied saddle numbness. On exam, lumbar range of motion was decreased in forward flexion secondary to pain, and he exhibited difficulty returning to neutral position. Motor exam revealed 4/5 strength in the EHL, tibialis anterior, biceps femoris muscle, and gastrocnemius on the right; otherwise 5/5 throughout. DTRs were 1+ at the ankle on the right; otherwise 2+ throughout and symmetrical. Plantar responses were flexor bilaterally. Gait was antalgic. He had difficulty heel and toe walking secondary to pain. Tandem walk was difficult secondary to pain. SLR was positive at 25 degrees, right greater than left. Sensory exam revealed a hypoesthetic region over the L5 and S1 distributions on the right to pinprick and light touch. Coordination was intact. MRI dated 11/14/14 was reviewed demonstrating HNP at L4-L5 paracentrally and toward the right with moderate facet and ligamentum flavum hypertrophy bilaterally contributing to right greater than left sided foraminal stenosis as well as lateral recess stenosis; retrolisthesis of L5 on S1 approximately 3-4 mm with associated HNP 4-5 mm paracentrally and toward the right also with contained annular tear also combined with facet and ligamentum flavum hypertrophy contributing to right-sided foraminal stenosis and lateral recess stenosis on the right; L4-L5 and L5-S1 demonstrating decreased disc height, disc desiccation, and internal disc disruption; straightening of the normal lumbar lordosis; moderate loss of disc height and disc signal intensity seen on sagittal images at the T11-T12 level; central spinal stenosis at T11-T12 and abnormal signal within the discal spinal cord which may represent edema or possible gliosis; no axial images were obtained at T11-T12. Surgery was again recommended.

12/30/14: UR. RATIONALE: The surgeon's impression of the MRI differs from the radiologist's report. The patient's urinary symptoms might relate to findings at T12-L1. No segmental instability has been documented to support a surgical fusion.

05/18/15: The claimant was evaluated. His medications were listed as gabapentin and tramadol. He complained of low back pain and bilateral leg pain as well as numbness. His prior treatment was listed as bracing, chiropractic,

physical therapy, and TENS. He reported sitting and medication as making the pain better. On exam, he had decreased sensation to pinprick in bilateral lower extremities in the L4 and L5 dermatomal distributions. SLR was positive at 75 degrees bilaterally. recommended bilateral lumbar transforaminal ESI at L4-L5 and L5-S1. He was prescribed a pain cream.

06/04/15: UR resulted in denial of L5-S1 transforaminal epidural steroid injection with fluoroscopy due to not meeting guideline criteria for radiculopathy.

07/02/15: The claimant was evaluated with complaints of 8/10 low back and right lower extremity pain. Exam was unchanged. Surgery was again recommended.

07/29/15: UR. RATIONALE: Based on the documentation provided, it is not clear as to what level(s) contribute to the patient’s symptoms/signs. Based on the MRI report, the L5-S1 level alone could explain both L5 and S1 nerve root symptoms/signs on the right. The clinical history and examination findings suggest lateral recess rather than central stenosis as contributing to unilateral radicular symptoms. In addition, plain x-rays have not documented segmental instability in the setting of a 1-2 mm L5-S1 retrolisthesis. I see no indication for complete facetectomies as outlined in the surgeon’s request. ODG are not met for the requested surgical procedures. Consideration might be given to updated imaging studies in the form of CT myelography to assess nerve root compression, segmental stability, and the conus medullaris.

08/12/15: UR. RATIONALE: The patient has back pain. The MRI shows a lesion at conus that needs to be addressed first. There is no indication at this time for a 2-level 360-degree fusion. The tumor must be addressed first. There is no demonstration of instability. Need to see imaging study.

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

The previous adverse decisions are upheld. This claimant’s lumbar MRI shows an abnormality at his conus level that needs to be addressed. He needs a dedicated MRI of the spinal levels where this conus lesion is located with and without contrast with axial, sagittal, and coronal views. He also needs a metastatic work up including head MRI and screening spine MRI with and without contrast to exclude drop metastasis from a lesion higher in his CNS. Once the spinal mass has been evaluated, his back and right leg pain can be treated by right-sided lumbar laminotomy/foraminotomy for decompression of the L3-L4, L4-L5, and L5/S1 levels. He has no need for an anterior/posterior fusion with instrumentation, as his lumbar x-rays show no instability. Therefore, the request for 2-day inpatient stay for an anterior lumbar interbody fusion at L4-L5 and L5-S1 with posterior lumbar decompression to include bilateral facetectomies thus predisposing the patient to iatrogenic instability, posterolateral fusion and pedicle screw instrumentation at L4-L5 and L5-S1 is not medically necessary.

ODG:

Fusion (spinal)	<p>Patient Selection Criteria for Lumbar Spinal Fusion: (A) <i>Recommended</i> as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:</p> <ul style="list-style-type: none"> (1) Spondylolisthesis (isthmic or degenerative) with at least one of these: <ul style="list-style-type: none"> (a) instability, and/or (b) symptomatic radiculopathy, and/or (c) symptomatic spinal stenosis; (2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level; (3) Revision of pseudoarthrosis (single revision attempt); (4) Unstable fracture; (5) Dislocation;
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	<p>(6) Acute spinal cord injury (SCI) with post-traumatic instability;</p> <p>(7) Spinal infections with resultant instability;</p> <p>(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;</p> <p>(9) Scheuermann's kyphosis;</p> <p>(10) Tumors.</p> <p>(B) <i>Not recommended</i> in workers' compensation patients for the following conditions:</p> <p>(1) Degenerative disc disease (DDD);</p> <p>(2) Disc herniation;</p> <p>(3) Spinal stenosis without degenerative spondylolisthesis or instability;</p> <p>(4) Nonspecific low back pain.</p> <p>(C) <i>Instability criteria</i>: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or 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 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)</p> <p>(D) After failure of two discectomies on the same disc [(A)(2) above], 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>(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. 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. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.</p> <p>(F) <i>Pre-operative clinical surgical indications</i> for spinal fusion should include all of the following:</p> <p>(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);</p> <p>(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;</p> <p>(3) Spine fusion to be performed at one or two levels;</p> <p>(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;</p> <p>(5) 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>(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;</p> <p>(7) 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:</p>
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	<p>I. <u>Symptoms/Findings</u> 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.</p> <p>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>(<u>EMGs</u> are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)</p> <p>II. <u>Imaging Studies</u>, 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. <u>MR</u> imaging 2. <u>CT</u> scanning 3. <u>Myelography</u> 4. <u>CT myelography</u> & X-Ray <p>III. <u>Conservative Treatments</u>, requiring ALL of the following:</p> <ul style="list-style-type: none"> A. <u>Activity modification</u> (not bed rest) after <u>patient education</u> (≥ 2 months) B. Drug therapy, requiring at least ONE of the following: <ul style="list-style-type: none"> 1. <u>NSAID</u> drug therapy 2. Other analgesic therapy 3. <u>Muscle relaxants</u> 4. <u>Epidural Steroid Injection</u> (ESI) C. Support provider referral, requiring at least ONE of the following (in order of priority): <ul style="list-style-type: none"> 1. <u>Physical therapy</u> (teach home exercise/stretching) 2. <u>Manual therapy</u> (chiropractor or massage therapist) 3. <u>Psychological screening</u> that could affect surgical outcome 4. <u>Back school</u> (<u>Fisher, 2004</u>) <p>For average hospital LOS after criteria are met, see <u>Hospital length of stay</u> (LOS).</p>
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Hospital length of stay (LOS)	<p>ODG hospital length of stay (LOS) guidelines:</p> <p>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) -- <i>Outpatient</i></p> <p>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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IRO REVIEWER REPORT TEMPLATE -WC

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)