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Notice of Independent Review Decision

DATE: January 28, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Extreme Lateral Interbody Fusion (XLIF) at L3-L4 with a Two (2) Day Length of Stay

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 Orthopaedic Surgery with over 42 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:

Xx/xx/xx: Employee Injury Report, Supervisor's Accident Report, Incident Report, Workers' Compensation Authorization for Treatment

Xx/xx/xx: Initial Evaluation

12/09/99: Employer's First Report of Injury or Illness

12/15/99: Letter

12/15/99: Workers' Compensation Authorization for Treatment

12/21/99: Workers' Compensation Information, Prescription, Letter of Medical Necessity

12/30/99: Injured Worker Status Report

01/17/00: Progress Note

01/28/00: Lumbar Discogram and CT Scan report

01/31/00: EMG Nerve Conduction Study report

02/01/00, 02/15/00, 03/02/00, 05/02/00, 05/16/00, 06/20/00, 07/11/00, 07/14/00,

07/19/00, 08/15/00, 09/19/00: Progress Note

02/07/00: History and Physical

02/08/00: Recommendation for Spinal Surgery

02/13/00: Records
03/01/00: History and Physical Exam Report
03/09/00: Office Visit
03/14/00, 06/29/00, 09/19/00, 04/16/02: Authorization Notice
03/16/00: Result of Spinal Surgery Second Opinion Process
03/23/00: Note
03/23/00: Preop Tests
03/28/00: Behavioral Medicine Evaluation
03/28/00: Preoperative Internal Medicine Consultation Report
03/29/00: Operative Report
04/01/00, 04/04/00: Records
04/05/00: Records
04/07/00: Operative Report
04/11/00: Infectious Disease Consultation Report
04/11/00: Bone Density Study Report
04/18/00: Progress Note
04/27/00, 05/11/00: Progress Note
06/09/00: Records
07/19/00: Physical Therapy Progress Note
07/27/00: Therapy Note
08/03/00: Office Note
08/08/00: Doctor's Medical Report and Work Status Form
08/16/00: Reevaluation
09/20/00, 03/28/03: Operative Report
10/09/00, 11/20/00, 03/24/03, 11/16/04, 01/12/05, 02/10/05, 04/19/05, 05/31/05,
07/19/05, 09/15/05, 11/07/05, 01/03/06, 02/14/06, 04/06/06, 10/31/06, 01/30/07:
Progress Note
10/24/00: FCE
11/02/00: Impairment Rating
04/08/02, 04/22/02, 04/29/02, 03/09/05: Progress Note
04/22/02: Procedure Note
04/21/04: Procedure Note
12/08/04: Presurgical History and Physical
12/08/04: Operative Report
02/22/05: MRI Lumbar Spine Report
03/09/05: Lumbar Spine Seven Views Report interpreted
03/21/05: Progress Notes
04/05/05: History and Physical Examination
04/15/05: Authorization
04/22/05: Memorandum
05/16/05: Lower NCV and EMG Report
05/24/05, 07/05/05: Progress Note
07/14/05: Consultation
08/01/05: UR
08/05/05: Behavioral Medicine Evaluation
08/18/05: Progress Note
04/06/06: W-Lumbar Spine 5 Views Report
04/12/06: Initial Chart Note

05/08/06: Procedure Report
05/08/06: CT Lumbar Spine Report interpreted
05/09/06, 11/08/06, 12/13/06, 02/14/07: Chart Note
05/22/06: Bone Growth Stimulator Prescription
05/23/06: UR
05/24/06: Re-dictation of lost dictation on chart note of 05/24/06
06/07/06: Chest X-ray Report interpreted
06/07/06: Medical Records
06/12/06, 06/13/06, 06/14/06, 06/15/06, 06/16/06, 06/17/06: Medical Records
06/13/06: Operative Report
06/13/06: Three Views of the Lumbar Spine report
06/17/06: Discharge Summary
06/19/06, 07/03/06: Medical Records
06/21/06, 07/26/06, 09/15/06: Chart Note
06/28/06: Urgent Request for Authorization
06/28/06: Lab Report
07/03/06: MRI Lumbar Spine report
07/05/06: Patient Account Worksheet
07/18/06: Bone Growth Stimulator Patient Agreement
07/21/06: Lumbar Spine Three Views report
08/01/06: Initial Evaluation
08/02/06, 08/04/06, 08/07/06, 08/09/06, 08/11/06, 08/16/06, 08/25/06, 09/18/06,
09/20/06, 09/22/06, 09/25/06, 10/04/06, 10/09/06, 10/11/06: SOAP Note
08/25/06, 09/11/06, 11/06/06, 12/06/06: Summary
08/29/06: UR
09/06/06: Acknowledgement of Reconsideration Request
09/06/06: W-Spine Lumbar 3 Views report
09/09/06: Daily Progress Copy
11/06/06: Lumbar Spine report
11/29/06: Admission Orders
12/03/06, 12/04/06: Medical Records
12/04/06: Procedure Note
12/28/06: UR
01/05/07: Medical Records
01/23/07: Operative Report
01/23/07: Lumbar Spine X-rays report
01/23/07: History and Physical
02/12/07: Lumbar Spine X-rays report
02/20/07: Initial Evaluation
03/29/07, 05/29/07, 11/27/07, 01/22/08, 04/15/08, 07/15/08, 11/11/08, 02/11/09,
05/12/09, 06/09/09, 10/06/09, 01/05/10, 02/02/10, 03/30/10, 06/22/10, 09/21/10,
11/16/10, 04/04/11, 09/19/11, 11/15/11, 02/07/12, 03/20/12, 06/12/12, 03/19/13,
04/16/13, 05/14/13, 07/09/13, 08/06/13, 09/03/13, 10/01/13, 10/29/13: Office Visit
05/09/07, 07/18/07, 07/23/08, 10/22/08, 12/17/08, 05/13/09: Chart Note
07/16/07: Lumbar Spine X-rays report
10/15/07: Procedure Report
11/07/07, 01/30/08, 04/09/08, 08/13/08, 02/11/09, 05/06/09, 05/20/09, 07/15/09,
09/23/09, 12/02/09, 02/24/10: Nurse Case Manager Visit

11/12/07, 02/15/08, 05/02/08, 08/08/08, 02/16/09, 07/30/09, 09/28/09, 03/05/10:
Progress Report
02/05/08, 07/08/08: Nurse Case Manager Conference
04/24/08, 09/10/08, 11/13/08, 12/02/08: UR
05/01/08: History and Physical
07/18/08, 05/08/09, 04/04/13, 09/10/13: Lumbar Spine X-rays report
10/13/08, 04/22/13: Lumbar Spine MRI report
12/15/08, 05/31/13: Operative Report
04/21/10: Left Knee X-rays report
06/20/11: RUR
01/23/13: MRI Chest report
01/23/13: MRI Orbit, Face, and Neck report
04/23/13, 05/22/13, 10/10/13: UR
05/14/13: Lab Results
09/18/13: New Patient Visit
10/30/13: Behavioral Medicine Evaluation
10/31/13: UR
11/27/13: Authorization Request
12/05/13: UR
12/09/13: Appeal Request
12/12/13: UR

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured while pulling up on a side door to close it on xx/xx/xx.

01/28/00: CT Scan of the Lumbar Spine with Intradiscal Contrast report interpreted. IMPRESSION: Degenerative disc space narrowing at L5-S1 with evidence of a left posterolateral annular tear at L5-S1. This was the level that was positive at provocative discography. Bilateral spondylosis at L5 without spondylolisthesis. Bilateral neural foraminal narrowing at L5-S1.

01/31/00: EMG Nerve Conduction Study. IMPRESSION: The study displays evidence of irritability of left lower lumbosacral paraspinous muscles on EMG but no evidence of frank denervation changes in this region nor in any other region of the left lumbar paraspinous muscles nor of the left lower extremity muscles. The nerve conduction study was entirely normal. This study is compatible with irritability of the left L5 or S1 root but with no evidence of any other electrophysiologic abnormality. The study suggests no injury to the nerve roots sufficient to cause any axonal degeneration nor any segmental demyelination at this time.

03/29/00: Operative Report. POSTOPERATIVE DIAGNOSIS: Lumbar radiculopathy with internal derangement of the L5-S1 disc. PROCEDURE: Complete anterior discectomy with decompression of the anterior epidural space and lateral recesses, L5-S1. Right anterior iliac bone graft. Internal fixation with two BAK cages, one proximity and one 17 x 20.

04/07/00: Operative Report. POSTOPERATIVE DIAGNOSIS: Status post anterior lumbar interbody fusion at L5-S1 with acute subsidence and compression fracture. Herniated nucleus pulposus, L5-S1, with left-sided radiculopathy. Spondylosis/spondylolisthesis of L5 on S1. PROCEDURE: Laminectomy and discectomy, L5-S1. Posterior spinal fusion, L5-S1, with instrumentation at L5 and S1. Bilateral nerve root explorations at the L5 and S1 levels. Iliac crest bone graft. Reconstruction of left iliac crest bone graft site. Iliac crest bone graft was performed through a separate fascial incision.

02/22/05: MRI Lumbar Spine report interpreted. IMPRESSION: L3-L4: Mild disc bulge. Borderline central stenosis. Slight narrowing inferior aspects of the neural foramen as above. L4-L5: Mild facet arthropathy. Minimal disc bulge without neural encroachment. L5-S1: Attempted prior fusion. No evidence for disc herniation or re-prolapse. Limited, however, negative for evidence of frank neural encroachment.

06/13/06: Operative Report. POSTOPERATIVE DIAGNOSIS: Internal disc disruption. Spinal stenosis. Radiculopathy. PROCEDURE: Posterior lumbar interbody fusion bilaterally L4-L5. Transverse process fusions. Total laminectomy. Foraminotomies. Pedicle fixation. Explantation pedicle fixation L5 to S1 bilateral (BacFix). Bone marrow aspiration left iliac crest x 3 with Jamshidi Needles. NeuroVision monitoring of nerve roots and pedicle screws x 4 hours.

01/23/07: Operative Report. POSTOPERATIVE DIAGNOSIS: Symptomatic pedicle fixation. Intact spinal fusion. PROCEDURE: Explantation pedicle fixation. Evaluate fusion integrity.

03/19/13: The claimant was evaluated for complaints of low back pain, hip pain, and lower extremity pain. On physical exam, he carried himself in a forward-flexed position. There was atrophy of the paraspinal muscles of the lumbar spine. Range of motion was limited in flexion and extension. There was marked spasm across the paraspinal muscles. PLAN: Continue Norco, Lyrica, and Lunesta. Start Tizanidine. Obtain lumbar spine x-rays.

04/04/13: Lumbar Spine 7-Views report. IMPRESSION: Interbody fusion at L4-L5. Cage fusion at L5-S1 in good position. Posterior and posterolateral fusion at L4, L5, and S1. Laminectomy changes at L4-L5. Minimal anterolisthesis of L3 vertebral body with reference to L4 in the standing lateral flexion view which gets reduced in the standing lateral extension view.

04/22/13: MRI of the Lumbar Spine report. IMPRESSION: Central and paracentral disc protrusion on the right side at L3-L4 with obliteration of epidural fat and impingement on the thecal sac. Moderate degree of central spinal canal stenosis at L3-L4. Interbody fusion at L4-L5, L5-S1 levels. Laminectomy changes at L4-L5, L5-S1 levels. No evidence of postoperative infection, discitis, pseudomeningocele, or arachnoiditis.

05/14/13: The claimant was evaluated for increased low back pain. He had a burning sensation over the buttocks extending over the right anterolateral thigh and calf. On exam, he had tenderness in the lumbar paraspinal segments. Range of motion was limited in flexion and extension. There was some dysesthesias over the right anterolateral thigh. He had a limping gait. SLR positive over the right lateral thigh and calf. Decreased sensation over the left L5 distribution. PLAN: Proceed with lumbar epidural steroid injection at L3-L4. Continue hydrocodone, Lyrica, Celexa, Lunesta, and Zanaflex.

05/31/13: Operative Report. POSTOPERATIVE DIAGNOSIS: Lumbar herniated nucleus pulposus. OPERATIVE PROCEDURE: Lumbar epidural steroid injection.

07/09/13: The patient was evaluated. It was noted that he received modest relief from his lumbar epidural steroid injection.

09/10/13: Lumbar Spine 5-Views report. IMPRESSION: 3-4 mm anterolisthesis of L3 vertebral body with reference to L4 in the standing lateral flexion view which gets partly reduced in the standing lateral extension view. Cage fusion at L5-S1 level. No other abnormalities identified.

09/18/13: The claimant was evaluated for back pain and bilateral lower extremity pain. It was noted that he had been treated with physical therapy and injections. On physical exam, DTRs were 2/4, equal and symmetric. Normal gait. Strength was 5/5. There was significant spinal tenderness in the paraspinal muscles. Bilateral SLR negative. No Waddell sign present. Normal sensation. Normal strength. Normal reflexes. Good range of motion. Spinal motion was with pain. ASSESSMENT: Severe spinal stenosis at L3-L4 above the level of prior fusion. There is a ligamentum flavum hypertrophy, facet hypertrophy, and disc protrusion noted. He has symptoms of neurogenic claudication in bilateral lower extremities with sensory loss in the L3-L4 dermatomes, particularly on the left leg. Also, 4/5 strength testing noted with knee extension and thigh atrophy noted. PLAN: Decompressive laminectomy at L3-L4. Due to the extent of decompression that is required at L3-L4, this will render the segment unstable. I will need to perform a significant facetectomy above the level of the previous fusion, which will create an iatrogenic instability and, therefore, require fusion at this level.

10/01/13: The claimant was evaluated for low back pain radiating into the lower extremities. On exam, there was tenderness over the lumbar paraspinal segments, worse with hyperextension and lateral bending. He did favor a forward-flexed position. SLR was positive for pain over the right lateral thigh and calf. He had a sensory in the right L5 distribution. PLAN: Palliate his symptoms until surgery.

10/29/13: The claimant was evaluated who planned to continue him on his Percocet as needed for pain and add Ambien for sleep disturbance.

10/30/13: The claimant was evaluated who cleared him from the psychological screening for surgical intervention.

12/05/13: UR. RATIONALE: This male apparently injured his back while pulling on xx/xx/xx. He has been treated with off work, TENS, medications, multiple facet blocks, epidural steroid injections, and psychometric exams. He has had four prior surgeries including L5-S1 fusion, posterior fixation and lateral mass fusion in 2000, and posterior lumbar interbody fusion at L4-L5 in 2006. He was noted on 10/30/13 to have back pain with pain shooting down both hips and legs. That report is from a behavioral health record evaluation that is incomplete. The only other records that we have is a review of records for a RUR. We do not have history or exam information from the requesting doctor. The current request is for extreme lateral interbody fusion at L3-L4 with two day LOS. We basically have no information to answer the 6 ODG preoperative surgical indications recommended criteria. Therefore, the medical necessity of the requested procedure is not established.

12/12/13: UR. RATIONALE: The documentation submitted reflects that the claimant sustained an injury on xx/xx/xx. The claimant has had four previous surgeries for pain or spine related problems. These include a fusion in 2001 and a second surgery in 2007 with excellent results but the pain returned in the last year. The claimant has been treated with physical therapy and injections. Currently, the claimant complaints of back pain, neck pain, and leg pain located on both sides. Physical examination shows significant spinal tenderness in the paraspinal muscles and pain with spinal motion with normal sensation, motor strength, and reflexes in the lower extremities. The claimant has severe spinal stenosis at L3-L4 above the level of prior fusion. The claimant has symptoms of neurogenic claudication in bilateral lower extremities with sensory loss in the L3-L4 dermatomes, particularly on the left leg. Radiology report x-ray of the lumbar spine 6 views reveals 3-4 mm anterolisthesis of L3 vertebral body with reference to L4 in the standing lateral flexion view which gets partly reduced in the standing lateral extension view. Radiology report MRI of the lumbar spine with and without contrast reveals central and paracentral disc protrusion the right side at L3-L4 level with obliteration of epidural fat and impingement of thecal sac with moderate degree of central spinal stenosis at L3-L4 level. Behavioral medicine evaluation report notes that based on the presurgical psychological screening, the claimant is clear for surgery with a fair to good psychosocial prognosis for pain reduction and functional improvement. The provider recommends decompressive laminectomy at L3-L4. Due to the extent of decompression that is required at L3-L4, this will render the segment unstable. The provider also recommends significant facetectomy above the level of previous fusion which will create an iatrogenic instability and therefore require fusion of this level. ODG-TWC states that XLIF is not recommended. In this case, the claimant continues to have pain in the lower back with significant deficits on examination despite prior conservative care. Submitted medical records note that there is evidence of 3-4 mm anterolisthesis of L3 vertebral body with reference to L4 based on lumbar spine x-ray. However, evidence based medicine guidelines do not support the request as additional studies are required to further evaluate and monitor the short and longer-term

safety, efficacy, outcomes, and complications of XLIF procedures. Thus, medical necessity for Extreme lateral interbody fusion (XLIF) at L3-L4 with a 2 day LOS is not established.

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

The previous adverse decisions are upheld. Based on the records provided, an extreme lateral interbody fusion is not recommended. The ODG do not recommend XLIF procedures. In this case, surgery is indicated for the claimant's spinal and foraminal stenosis and instability, such as a posterior lateral fusion and pedicle fixation. However, the request for Extreme Lateral Interbody Fusion (XLIF) at L3-L4 with a Two (2) Day Length of Stay is not medically necessary.

ODG:

Fusion, endoscopic	<p>Not recommended. At best, endoscopic spinal fusion should be limited to conditions outlined for open fusion above (spinal fracture, dislocation, or spondylolisthesis). (Knight-Spine, 2003) (Arvan, 2009) Endius, Inc., Plainville, MA, produces the FDA-approved Atavi™ Atraumatic Spine Fusion System. NuVasive, San Diego, CA, offers the XLIF® procedure for lumbar fusion to overcome the obstacles of anterior and posterior fusion. This minimally invasive lateral access method may provide benefits to patients compared to traditional fusion, including reduced surgery time, less blood loss, shorter hospital stays, and significantly faster recovery time. Return to normal activities is suggested to be 4-6 weeks after XLIF versus 6 months or longer with traditional lumbar fusion. XLIF has a unique set of complications, including neural injuries, psoas weakness, and thigh numbness. Additional studies are required to further evaluate and monitor the short and long-term safety, efficacy, outcomes, and complications of XLIF procedures. (Arnold, 2012)</p>
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 - 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, 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>
<p>Hospital length of stay (LOS)</p>	<p>ODG hospital length of stay (LOS) guidelines: 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>

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)**