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Notice of Independent Review Decision

DATE OF REVIEW: May 22, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Hardware Removal Right L4-S1 w/Exploration Fusion, Possible Revision 22852, 22830, Inpatient LOS x 3 Days 99356

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

This physician is Board Certified by the American Board Orthopedic Surgeons with over 40 years of experience.

REVIEW OUTCOME:

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

Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

02/12/08: Consultation by
07/31/08: Followup visit by
08/18/08: Followup visit by
09/26/08, 11/20/08, 2/12/09, 6/23/09, 7/21/09, 08/11/09, 09/10/09, 10/20/09, 12/01/09, 04/06/10, 5/18/10, 8/17/10, 9/16/10, 10/19/10: Followup visits by
04/13/10: Functional Capacity Evaluation by
09/24/10: Operative Note by
09/24/10: Discharge Summary by
10/28/10: Physical Therapy Initial Evaluation by and
11/16/10: Followup visit by
12/14/10: Followup visit by
01/18/11: Functional Capacity Evaluation by
01/18/11: Work Conditioning Daily Note from
01/25/11: Followup visit by

02/02/11: Physical Therapy Initial Evaluation
05/17/11: Followup visit by
08/14/11: CT Lumbar Spine W/O Contrast performed at and interpreted by
08/30/11: Followup visit by
10/24/11: Peer Review by
01/19/12: Followup visit by
02/28/12: Followup visit by

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who sustained a work-related injury to the low back on xx/xx/xx. He is status post lumbar fusion with subsequent hardware removal and lumbar fusion revision.

02/12/08: The claimant was evaluated by who noted that the claimant complained of back pain radiating into the buttocks, thigh, leg, foot, and toes. indicated that the claimant had undergone treatments including pain medications and physical therapy. On physical examination, he had normal toe/heel walk bilaterally. Lumbar ROM was 30 degrees in flexion without pain, 40 degrees in extension without pain, 20 degrees leftward rotation without pain, and 40 degrees rightward rotation without pain. He had moderate paraspinal tenderness to the left at L3, L4, L5, and S1 to palpation and moderate left paraspinal muscle spasms. He had a positive SLR. Atrophy in left calf 1 cm was noted. There was decreased sensation to light touch on the left lateral foot. X-rays demonstrated a questionable pars defect at L5. 2007 MRI demonstrated a posterolateral HNP at L5-S1 and L4-L5 and IDD at L4-S1. planned ESI x 2 with. Consideration was to be made for discogram versus laminectomy surgery at next visit.

09/24/10: Operative Report by. Postoperative Diagnosis: Unilateral nonunion L5-S1, L4-L5, status post lumbar fusion. Procedures: 1. Modifier 22 because of previous surgery. 2. Hardware removal L4 though S1 bilaterally. 3. Exploration of fusion L4 through S1 bilaterally with identification of nonunion on the right. 4. Posterior lateral fusion L4-L5, L5-S1. 5. Posterior lateral instrumentation L4-L5, L5-S1. 6. OsteoCell and Allograft placement.

10/19/10: The claimant was evaluated by who noted that he complained of pain described as sharp, burning, and dull ache. Pain was 4 out of 1/10. He complained of tightness in the lower back. He had numbness in both feet. He had recently had an episode of groin numbness and tingling with difficulty urinating. Medications included Advil, Ultram, Valium, Norco, ibuprofen, and Flexeril. On physical examination, his lumbar incision was healed. X-rays of the lumbar spine dated 10/19/10 demonstrated hardware present right L4 and S1 and cage present L4-L5 and L5-S1. IMPRESSION: Painful hardware, S/P fusion of the lumbar spine, and radiculopathy L4. PLAN: We want to get him started in water therapy and then we will see him back in one month.

10/28/10: The claimant was evaluated at status post lumbar fusion revision with decreased ROM and strength, increased low back pain, and impaired soft tissue/joint mobility. On this visit, the claimant stated that he was experiencing less pain than compared to before the surgery but was still unable to work or complete all daily activities. He demonstrated decreased ROM, strength, increased pain, and decreased scar mobility due to post-surgical deficit. It was noted that he would benefit from skilled therapy to address the deficits listed above using the following interventions: modalities for pain relief, soft tissue mobilization, joint mobilizations, strengthening and ROM activities, balance and gait activities, endurance activities including recumbent bike, step, and elliptical, and patient/family education as well as aquatic therapy prior to land therapy.

11/16/10: The claimant was evaluated by for a follow up visit after surgery of the lumbar spine performed on 9/24/10. He complained of aches in the muscles and numbness in both legs. Pain was rated 3/10. Medications included Flexeril, Norco, Ultram, Valium, and ibuprofen. On physical examination, his lumbar incision was healing on the left side. Paraspinal palpation had no tenderness. PLAN: 1. Unspecified mechanical complication of internal orthopedic device, implant, and graft (painful hardware): I want to evaluate him for work conditioning or work hardening at the next visit.

12/14/10: The claimant was evaluated by who reported that he had undergone no therapy due to denial. He complained of numbness right middle toe, back spasms, and catching pain on the right side rated as 3/10. Medications included Norco, valium, Flexeril, and ibuprofen. X-rays demonstrated L4-S1 with screw at L4 and S1 with rod and PEEK at L4-S1. Fusion looked solid. On physical examination, he had tenderness over the hardware on the right side. PLAN: 1. Unspecified mechanical complication of internal orthopedic device, implant, and graft (painful hardware): Start Relafen Tab, 500 mg, 1 tab orally b.i.d. x 30 days, #60 with 2 refills.

01/25/11: The claimant was evaluated by. He complained of numbness in the right middle toe, back spasms, and catching pain on the right side rated as 3/10. Medications included Norco, valium, Flexeril, and ibuprofen. On physical examination, his incision was well healed with no sign of infection. There was tenderness along the incision site. Mild paraspinal spasm was present. ASSESSMENT: This patient is doing well. I feel the patient should proceed with an evaluation for work conditioning or definitely proceed with some type of physical therapy. Physical therapy is mandatory postoperatively for reconditioning of the spinal musculature. Please ask patient to proceed with physical therapy. The patient stated that he is using a nicotine gum. I informed him that he cannot use nicotine gum and needed to stop using it today. He also needs to stay away from chewing tobacco. Next visit, I would like x-rays.

02/22/11: The claimant was evaluated by who noted that the he complained of pain in his right lower back and numbness and tingling with "fire" sensation I the

feet and frequently in his right anteromedial leg. He noted muscle atrophy in his legs since onset of injury. Notes indicate his pain rating as 3-4/10 on VAS. ROM: Flexion 10 degrees with severe pain requiring 1-2 minutes to recover, extension 10 degrees, lateral flexion 20 degrees bilaterally. Positive SLR tests bilaterally. PLAN: The patient will be seen 2-3 times per week for 4 weeks. The following interventions may be utilized: Therapeutic exercise for ROM and strengthening, patient education to facilitate self-management of symptoms and to prepare patient for discharge, HEP to facilitate carryover to functional activities, manual therapy to improve soft tissue dysfunction, and modalities to decrease pain, decrease edema, and prepare tissues for mobilization.

05/17/11: The claimant was evaluated by who noted that the claimant had good results with physical therapy but did have some increased pain after therapy. He complained of catching pain on his right side believed to be his hardware rated at 3/10. Medications included Valium, ibuprofen, Flexeril, and Norco. X-rays dated 5/17/11: "Screw at L4 and S1 with PEEK cages at L4-S1. There is a halo around the right S1 screw. There appears to be a solid fusion at L5-S1 and questionable fusion at L4-L5." On physical examination, paraspinal palpation had positive tenderness. PLAN: I want to get a CT scan to evaluate his fusion since there is a halo around the S1 screw. I am concerned that he does not have a fusion and that is why he continues to have back pain.

08/14/11: CT Lumbar Spine W/O Contrast. IMPRESSION: Status post anterior and posterior fusion at the L4-L5 and L5-S1 levels with removal of left posterior fusion hardware. There is evidence for loosening of the right S1 pedicle screw. Although difficult to ascertain due to metal artifact, it appears that the intervertebral bone grafts at L4-L5 and L5-S1 are solidly incorporated. No evidence for spondylolisthesis within or adjacent to the fused segment. No evidence for spinal stenosis or neural foraminal narrowing within the lumbar spine.

08/30/11: The claimant was evaluated by who noted that he complained of aching pain and some catching on his right side believed to be his hardware rated at 5/10. Medications included ibuprofen, Flexeril, Ultram, Tramadol HCL, Norco, and valium. On physical examination, paraspinal palpation had positive spasms. Atrophy was not present. Sensation was intact to light touch bilaterally. Posterior tibial pulses were 2+ bilaterally. SLR positive on the right hamstring. The incision was healed. ASSESSMENT: This patient has a screw that is loose at S1. The fusion appears to be solid. The patient will call when he is ready to have his hardware removed. I discussed hardware removal with the patient in detail. The patient is having cardiac ablation treatment, and we will have to wait until that has been complete.

01/19/12: The claimant was evaluated by who noted that he complained of pain, which was manageable with pain medication. He described the pain as catching in the right low back with pressure-like jabbing on the right side of the low back.

Pain was rated 5/10. Medications included ibuprofen, Flexeril, Ultram, Valium, and Norco. On physical examination, paraspinal palpation had tenderness over hardware that was very severe. ASSESSMENT: The patient had a lumbar fusion in the past that involved placement of instrumentation. At the present time, the patient does have a solid fusion. However, there is a halo around the screw indicating that the patient's screws are loose. Loose screws cause significant pain when they are moving inside of a bone structure. The standard of care for treatment is hardware removal. The patient has been denied surgical treatment which would be the standard of care for this problem. Please re-evaluate the patient's case. I would like him to proceed with the necessary treatment which falls within the realm of the standard of care.

02/28/12: The claimant was evaluated by who noted that he complained of catching on the right side of the lower back, stinging down the left thigh, and numbness in bilateral feet. Pain was rated 6/10. Treatments for the pain have included anti-inflammatory drugs and Aleve. Medications included ibuprofen, Flexeril, Ultram, Valium, and Norco. On physical examination, his gait was coordinated. Paraspinal palpation had tenderness over hardware that was very severe, positive muscle spasm. Sensation was decreased to light touch on the left S1 nerve root. Left SLR positive at S1 nerve root. ASSESSMENT: This patient is here for followup. He still has pain over his hardware. He wanted to discuss hardware removal. I think this is reasonable. He will return when he is ready to proceed with surgery. At the present time, he does not want to proceed with surgery because of family issues.

03/30/12: UR performed by. Reviewer comments: The medical report dated 02/28/12 indicates that the patient has low back and bilateral leg pain. On examination of the lumbar spine, there is severe tenderness over the hardware, positive muscle spasm, and decreased sensation to light touch on the left S1 nerve root. CT scan of the lumbar spine dated 6/14/11 revealed that there is evidence of loosening of the right S1 pedicle screw. This is a request for hardware removal right L4-S1 with exploration fusion possible revision, and inpatient LOS for three days. However, the medical report failed to objectively document exhaustion and failure of conservative treatment such as activity modification, home exercise training, oral pharmacotherapy, and Physical Therapy. There are no noted VAS pain scales, and Physical Therapy notes documenting a lack of progress in several attempts. There is no documentation provided with regard to the failure of the patient to respond to recent evidence-based exercise program in the reviewed report. There is no evidence that the patient is unlikely to gain clinically significant functional response from continued treatment from less invasive modalities. The maximum potential of conservative treatment done was not fully exhausted to indicate a surgical procedure. Also, there is no documented radiologic evidence of instability. As per CT scan, "it appears that the intervertebral bone grafts at L4-5 and L5-S1 are solidly incorporated. There is no evidence for spondylolisthesis." Moreover, more recent x-rays of the lumbar spine were not provided. The psychological

evaluation for the procedure was also not provided. Hence, the medical necessity of this request has not been facilitated.

04/30/12: UR performed by. Reviewer comments: This is a request for an appeal of hardware removal right L4-S1 with exploration fusion possible revision and inpatient with length of stay for three days. The previous determination was non-certified due to lack of documentation of exhaustion of conservative treatment and recent diagnostic imaging. However, there were still no medical records sent to document exhaustion of recommended conservative treatments such as oral pharmacotherapy and Physical Therapy. There were no recent serial PT progress notes to document response to treatment. The recent diagnostic imaging report of x-rays of the lumbar, to document current status of spine and exclude other possible pain generators, was not submitted for review. The CT scan did not reveal pseudoarthrosis at the L4-S1 levels. Hence, the previous determination is upheld. Consequently, the other request is deemed not substantiated.

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

The previous adverse decisions are partially overturned. The above records were reviewed. After reviewing these records, it is my opinion that the claimant has exhausted all conservative treatment since his last surgery to control his back pain. On x-ray and CT scan, evidence of loose hardware is shown, and this can lead to significant back pain. I would recommend removal of the loose hardware. I would recommend it be limited to the posterior interpedicular screws and rods and not to include the interbody cage. I would not recommend exploration of the fusion or revision. He has already had two fusions. If he has not fused by now, a third fusion is not likely to be successful. I also feel that his surgery can be done with a 24-hour stay rather than requiring a 3-day hospitalization. Per Official Disability Guidelines, hardware should be removed in the case of persistent pain after ruling out other causes of pain.

ODG:

Hardware implant removal (fixation)	Not recommend the routine removal of hardware implanted for fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure. The decision to remove hardware has significant economic implications, including the costs of the procedure as well as possible work time lost for postoperative recovery, and implant removal may be challenging and lead to complications, such as neurovascular injury, refracture, or recurrence of deformity. The routine removal of orthopaedic fixation devices after healing remains an issue of debate, but implant removal in symptomatic patients is rated to be moderately effective. Many surgeons refuse a routine implant removal policy, and do not believe in clinically significant adverse effects of retained metal implants. For more information and references, see the Ankle Chapter .
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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).

Hospital length of stay (LOS)	<p>Recommend the median length of stay (LOS) based on type of surgery, or best practice target LOS for cases with no complications. For prospective management of cases, median is a better choice than mean (or average) because it represents the mid-point, at which half of the cases are less, and half are more. For retrospective benchmarking of a series of cases, mean may be a better choice because of the effect of outliers on the average length of stay. Length of stay is the number of nights the patient remained in the hospital for that stay, and a patient admitted and discharged on the same day would have a length of stay of zero. The total number of days is typically measured in multiples of a 24-hour day that a patient occupies a hospital bed, so a 23-hour admission would have a length of stay of zero. (HCUP, 2011)</p> <p>ODG hospital length of stay (LOS) guidelines:</p> <p>Lumbar Fusion, posterior (<i>icd 81.08 - Lumbar and lumbosacral fusion, posterior technique</i>) 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</p> <p>Lumbar Fusion, anterior (<i>icd 81.06 - Lumbar and lumbosacral fusion, anterior technique</i>) 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</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)**