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Notice of Independent Review Decision

DATE OF REVIEW: 04/08/09

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: Kyphoplasty, x-ray under fluoro

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

Board Certified Orthopedic Surgeon (Joint)

REVIEW OUTCOME

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. 10/07/08 thru 03/16/09
2. M.D., 10/23/08, 12/04/08, 01/08/09, 01/29/09
3. Imaging report, 01/29/09
4. 02/16/09, 03/09/09
5. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee was working on a rail car when he fell approximately twenty feet and injured his low back and right side of his body. The employee did not lose consciousness and was able to ambulate at the scene. There was no weakness, numbness, tingling, paresthesias, or loss of bowel or bladder control. The employee experienced severe right wrist pain with manipulation and low back pain. Past medical history was negative and past surgical history was negative. The employee had no known drug allergies and was not taking any current medications.

The employee was seen on the same day at Medical Center . His physical examination revealed gross deformity of the right wrist. There was no tenderness to palpation over the anatomic snuff box as well as the distal radius dorsally and volarly. There was no evidence of external fracture. The right upper extremity demonstrated full range of motion to the shoulder, elbow, and fingers. The wrist was limited secondary to pain. Sensation was intact to the median, ulnar, and radial nerve distributions. The extensor hallucis longus finger flexion and extension, as well as finger abduction was intact. There was normal biceps and triceps strength bilaterally. The employee had a good palpable radial pulse. There was good strength resistance of approximately 4/5 in hip flexors, hip adduction, abduction, knee flexion, knee extension, plantar flexion, dorsiflexion, and EHL bilaterally. Sensation was intact to light touch in all distributions. Reflexes were not hyperreflexive. There was no clonus or Babinski's noted. There was negative Hoffman's. Imaging two views of the right radius showed nondisplaced distal radius fracture with possible articular surface component indicating a die punch lesion with a minimally displace scaphoid waste fracture. No other fracture was seen. Imaging CT revealed a T12 superior endplate fracture with compression component with a fracture involving the right lateral aspect of the superior vertebral body. There was minimal loss of height with kyphosis at that level measuring approximately 5 degrees. The assessment was T12 superior endplate fracture with compression component, right distal radius fracture nondisplaced, and right scaphoid wrist fracture minimally displaced. The plans were an open reduction/internal fixation of the right wrist fracture and treat conservatively with a brace for the T12 fracture.

The employee began office follow-up on 10/23/08 at the . The initial provider was P.A. The employee continued to complain of pain on that date as being 7/10 but improving with the back brace. The employee denied previous an incidence of back injuries. Upper and lower extremities show 5/5 strength without evidence of sensory or neurologic deficits. There was tenderness to palpation in the thoracolumbar junction. There was no significant paraspinal spasms noted. There were no surgical scars. The appearance of the right wrist fracture was not significant at this point. X-rays and previous treatment were reviewed, and the plan was to continue current treatment, in particular using a brace to treat the T12 fracture, and further recommendations consisted of brace use during the day. Follow-up was to be in approximately one week, and then he was to follow-up in four weeks.

On 12/04/08, the employee followed up at the. The employee complained of some increase in lumbar spasms, although he seemed improved. The x-rays revealed a minor settling of the fracture when compared with a previous x-ray which was expected. The plan was to continue the current regimen and follow-up in one month.

On 01/08/09, the employee followed up at the. Again, the provider was. The employee had been doing well and was still notably tender over the thoracolumbar junction. He continued to report right sided buttock pain and some radiating pain down the posterior aspect of his leg into his heel. With these

new radicular findings, the plan was to obtain MRI of the lumbar spine. The employee started physical therapy for his right arm, and results were pending.

On 01/29/09, the employee followed up for review of the MRI of the lumbar spine. There were early signs of degenerative disc disease from L3 to the sacrum, but these were considered extremely mild. The T12 compressive fracture still showed signs of acuity based on the MRI scans. The comment was made that there was expectation that the fracture should have healed by that time. The plan presented to the employee, given the fact that there was still some acuity of the fracture after four months, was for him to have it treated through kyphoplasty or vertebroplasty. The general nature of both procedures was discussed with the employee, and he wished to proceed at this time.

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

Based upon the guidelines set forth for indications of kyphoplasty, which include patients of 50 years old or greater, there is a glaring contraindication to the use of this procedure at this time. Fracture activity can remain present on bone scan and MRI scan for six to eight months after vertebral compression fracture, so this is not uncommon. The determination at this time is to uphold the denial for approval of kyphoplasty. It is not indicated in this age group.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

The ***Official Disability Guidelines***, 13th Edition, The Work Loss Data Institute.

Kyphoplasty:
Recommended for employees with delayed healing of vertebral compression fractures. In patients with osteolytic fractures secondary to multiple myeloma, kyphoplasty yields quick pain relief, and is associated with a statistically significant improvement in generic health outcome measures. (Lieberman, 2003) (Garfin, 2002) A recent systematic review of 69 clinical studies concluded that a large proportion of subjects had some pain relief, including 87% with vertebroplasty and 92% with kyphoplasty; vertebral height restoration was possible using kyphoplasty and for a subset of patients using vertebroplasty; cement leaks occurred for 41% and 9% of treated vertebrae for vertebroplasty and kyphoplasty, respectively; and new fractures of adjacent vertebrae occurred for both procedures at rates that are higher than the general osteoporotic population but approximately equivalent to the general osteoporotic population that had a previous vertebral fracture. (Hulme, 2006) Balloon kyphoplasty can be performed with low periprocedural morbidity and can result in clinical improvement, report investigators in the first large, randomized, long-term study of spinal augmentation, known as the Fracture Reduction Evaluation (FREE) trial, published in *The Lancet*. Although the trial

results point to the safety and efficacy of kyphoplasty, investigators note that the benefits were not long lasting. For most outcome measures, the differences between kyphoplasty treatment and control were diminished at 12 months, because the nonsurgical group improved over time, probably as a result of fracture healing. Spinal augmentation procedures, including balloon kyphoplasty and vertebroplasty, have been in routine clinical use for more than a decade, but this is the first large, randomized trial to confirm previous case reports and smaller trials suggesting benefit. (Wardlaw, 2009) See also Vertebroplasty. (Kyphoplasty is a newer procedure, and some clinicians have concluded it is superior to vertebroplasty.)

Indications for Surgery -- Kyphoplasty

(1) Presence of unremitting pain and functional deficits due to compression fracture from osteolytic metastasis, myeloma, hemangioma, osteoporotic compression fractures;
(2) Lack of satisfactory improvement with medical treatment (e.g. medications, bracing, therapy);
(3) Absence of alternative causes for pain such as herniated intervertebral disc;
(4) Affected vertebra is at least one-third of its original height. (Ledlie, 2006)