MEDICAL CONTESTED CASE HEARING NO. 14009

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUES

A contested case hearing was held on September 24, 2013 to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization that Claimant is not entitled to a Kyphoplasty at levels T6-7 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by LS, ombudsman.
Respondent/Carrier appeared and was represented by JF.

BACKGROUND INFORMATION

Claimant was injured in the course and scope of his employment when he fell from about twelve feet, sustaining a compression fracture, chest injury, and a scalp injury. Claimant had various treatments but because of continued pain, additional diagnostics including a CT scan were obtained that showed a T6-7 compression fracture. As a result, Claimant's doctors submitted a request for a Kyphoplasty at levels T6-7.

Claimant's request for Kyphoplasty at level T6-7 was considered by two utilization review agents and an IRO. All concluded that the request for the Kyphoplasty does not meet the requirements of the *Official Disability Guidelines* (ODG).

Evidence Based Medicine (EBM)

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is further defined in Texas Labor Code Section 401.011

(18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308(s), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

In reference to Kyphoplasty, the ODG provides:

> Kyphoplasty
> Recommended as an option for patients with pathologic fractures due to vertebral body neoplasms, who may benefit from this treatment, but under study for other vertebral compression fractures, consistent with recent higher quality discouraging studies of a similar procedure, vertebroplasty (Kallmes, 2009) (Buchbinder, 2009), and if used for osteoporotic compression fractures should be restricted to selected patients failing other interventions (including bisphosphonate therapy) with significant unresolving pain. However, a recent study has suggested that kyphoplasty is no better than vertebroplasty for osteoporotic compression fractures. (Liu, 2010) There may be highly selected patients who were outside the scope of the two high quality trials of vertebroplasty above, who might still derive benefit from these procedures, for example, with three or more multiple simultaneous compression fractures despite bisphosphonate therapy, or pathologic fractures due to vertebral body neoplasms. (McGirt, 2009) This procedure had been recommended for patients 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.)

Recent research: A prospective randomized clinical study comparing balloon kyphoplasty versus vertebroplasty for treatment of osteoporotic vertebral compression fracture with 6-month follow up concluded that there was little difference in outcome between the treatment groups. (Liu, 2010) This study of clinical and radiological results after kyphoplasty in patients with vertebral body compression fractures due to spinal metastasis and multiple myeloma concluded that kyphoplasty is a safe and effective procedure for this condition. (Dalbayrak, 2010) This cohort study concluded that kyphoplasty presents a very safe and effective procedure for the treatment of vertebral osteolyses and fractures caused by multiple myeloma. (Huber, 2009) A recent technology assessment by the California Technology Assessment Forum (CTAF) recommended that balloon kyphoplasty with PMMA meets CTAF criteria for safety, effectiveness and improvement in health outcomes for the treatment of recent (< 3 month old) osteoporotic vertebral compression fractures confirmed by MRI, but it does not meet CTAF criteria for the treatment of chronic (>3 month old) osteoporotic, traumatic, or pathologic vertebral compression fractures. (Karliner, 2010) The AAOS made a strong recommendation against vertebroplasty for treatment of spinal compression fractures, but they said kyphoplasty may be an option for

neurologically intact patients presenting with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms, but the strength of this recommendation was weak. (Esses, 2010) In this RCT of patients with an acute/subacute vertebral compression fracture due to osteoporosis, balloon kyphoplasty was not shown to be cost-effective compared with standard medical treatment. (Fritzell, 2011)

Indications for Surgery – Kyphoplasty

(1) Presence of unremitting pain and functional deficits due to compression fracture from:
   (a) Osteolytic metastasis, myeloma, hemangioma [Recommended]
   (b) Osteoporotic compression fractures [Under study];
(2) Lack of satisfactory improvement with medical treatment (e.g. medications, bracing, therapy);
(3) Absence of alternative causes for pain such as herniated intervertebral disk by CT or MRI;
(4) Affected vertebra is at least one third of its original height. (Ledlie, 2006)
(5) Fracture age not exceeding 3 months, since studies did not evaluate older fractures.

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

As noted above, because of because of continued pain, Claimant's doctors submitted a request for Kyphoplasty at levels T6-7. As also noted above, the request for Kyphoplasty at level T6-7 was considered by two utilization review officers and the IRO. All concluded that the request for treatment did not meet the ODG requirements.

On March 6, 2013, the initial utilization review agent, an orthopedic surgeon, denied certification of the treatment noting:

> Criteria used in analysis: Patient has persistent back pain. There is a compression fracture with kyphotic deformity on imaging. There is edema at the bone indicating persistent fracture. There was a failure of medication, activity modification. There is severe back pain. There is retropulsion of fragments of 3mm at T6 on imaging with 11mm of space for the canal. The fracture is more than 3 months old. There is no follow-up exam or clinical rationale from the treating Dr. [sic.] to interpret the MRI and determine safety or efficacy of the plan for kyphoplasty given the MRI findings. There is no history of PT or bracing. Therefore, the request is not medically necessary per evidence based guidelines.

The review agent cited ODG guidelines, and based on the clinical information and using evidence based peer-reviewed guidelines, did not certify the treatment.

After a request for reconsideration, a second utilization review agent reviewed the requested treatment on April 4, 2013. The reviewer considered the recommendations of the previous review and then noted:

> It is recommended that if kyphoplasty is to be performed that it occur within two months of the injury. Medical necessity has not been established. Vertebroplasty may be warranted.

The IRO decision was issued on June 7, 2013 by a board certified interventional radiologist. The reviewer outlined the records provided for review as well as the patient clinical history and noted:

> According to the multi-specialty *American College of Radiology White paper*: "The major indication for vertebral augmentation is the treatment of symptomatic osteoporotic vertebral body fracture refractory to medical therapy." "Failure at medical therapy is defined as:
> (1) For a patient rendered non-ambulatory due to pain or pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy.
> (2) For a patient with sufficient pain from weakened or fractured vertebral body physical therapy is intolerable, pain persisting despite 24 hours of analgesic therapy.
> (3) For any patient with weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion or constipation due to the analgesic therapy necessary to reduce pain to a tolerable level."

The IRO noted Claimant was able to ambulate and tolerate physical therapy. The IRO considered a note from Advance Imaging of February 19, 2013, indicating that Claimant's pain had decreased to 5/10, was improved with Ibuprofen, and that Claimant was able to work light duty. The IRO also considered December 2012 physical therapy notes that indicate Claimant's thoracic pain was at a 0/10. The IRO concluded:

> In summary, this patient was able to ambulate, tolerate physical therapy and work light duty as soon as one month after his injury. He cannot be considered as a failure of medical therapy. He does not meet the indications for vertebral augmentation or kyphoplasty at this time.

Claimant testified at the hearing that he has continued to be in pain despite the provided treatment. Claimant is unsure if his doctors continue to believe that the requested treatment would be beneficial. However, Claimant believes that he needs some form of additional treatment. Claimant did not provide any medical documentation that directly responded to the IRO decision.

Claimant did not meet the evidentiary standard required to overcome the IRO decision and the preponderance of the evidence is not contrary to the IRO's determination that the Claimant is not entitled to a Kyphoplasty at levels T6-7 for the compensable injury of (Date of Injury).

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

   B. On (Date of Injury), Claimant was the employee of (Employer), Employer.

2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. Claimant sustained a compensable injury in the course and scope of his employment with Employer on (Date of Injury).

4. A Kyphoplasty at levels T6-7 is not health care reasonably required for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

2. Venue is proper in the (City) Field Office.

3. The preponderance of the evidence is not contrary to the decision of the IRO that a Kyphoplasty at levels T6-7 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to a Kyphoplasty at levels T6-7 for the compensable injury of (Date of Injury).

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **CASTLEPOINT NATIONAL INSURANCE COMPANY** and the name and address of its registered agent for service of process is

CT CORPORATION SYSTEM
350 NORTH ST. PAUL STREET
(CITY), TX 75201

Signed this 3rd day of October, 2013.

Katie Kidd
Hearing Officer