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Notice of Independent Review Decision

DATE OF REVIEW: 12/01/2009

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Thoracic Kyphoplasty at T11-12

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 08-18-09 Post contrast chest CT scan, abdomen CT, Pelvis CT and Thoracic-lumbar CT read by Dr.
- o 08-31-09 Thoracic MRI read by Dr.
- o 09-16-09 MRI report thoracolumbar spine read by Dr.
- o 09-16-09 Radiograph report from Dr.
- o 09-16-09 Consultation report from Dr.
- o 10-01-09 Medical report from Dr.
- o 10-01-09 Preauthorization request from Dr.
- o 10-07-09 Adverse Determination Letter
- o 10-07-09 Phone Note - Attempt to contact reviewer from Dr.
- o 10-20-09 Acknowledgement of Reconsideration request
- o 10-21-09 Reevaluation report from Dr.
- o 10-27-09 Adverse Determination Letter for Reconsideration
- o 10-29-09 Appeal letter from Dr.
- o 10-31-09 Request for appeal from Dr.
- o 11-10-09 Request for IRO from the Claimant
- o 11-11-09 Confirmation of Receipt of Request for IRO from TDI
- o 11-12-09 Notice of Case Assignment of IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a male who sustained an injury to the thoracic spine on xx/xx/xx when he stepped on loose material and fell about 12 feet off a roof.

The patient underwent post contrast CT scans on xx/xx/xx: The chest exam was unremarkable. The abdominal scan was unremarkable. The lumbar exam was unremarkable. The thoracic study revealed a very minimal anterior-superior compression fracture of the T11 vertebral body, involving the superior endplate, without evidence of posterior element involvement, malalignment or retropulsion. There is noted to be some levoscoliosis of the lower mid thoracic vertebral column.

Thoracic MRI was performed on August 31, 2009 and given impression: Anterior compression fracture of the T11 vertebra with 10% loss of vertebral height. Otherwise, negative MRI of the thoracic spine. Lumbar MRI impression noted a normal study.

The current provider initially examined the patient in consultation on September 16, 2009 for upper back pain and low back pain that radiates into both legs. Imaging revealed a small anterior compression fracture of the superior endplate of T11 vertebral body. He was given a back brace. He was returned to light duty on August 21, 2009. He reports constant upper back pain of 7/10 that does not radiate to the arms. He describes the pain as burning. The pain increases when he extends his arms. He reports low back pain that radiates into both legs. He sometimes takes more than four Norco daily for pain. He is also using Flexeril. He smokes half pack of cigarettes daily. He reports numbness and tingling in the legs. He is 5' 8" and 160 pounds. Gait is antalgic. Motor strength, sensation and reflexes are normal. There is severe tenderness to palpation in the thoracic spine with full range of motion. He has a closed thoracic fracture and lumbar radiculopathy. The patient states despite his high pain level he is not ready to consider the possibility of a kyphoplasty.

The provider took x-rays of the thoracic spine on September 16, 2009 and provided an interpretation of: 30% fracture of T11. There is no other abnormality. A variation in the upper part of T12 is also seen in the signal change on the T1 images, compatible with a fracture at that level as well.

Thoracolumbar MRI was performed on September 16, 2009 under direction of the provider who interpreted the films: The study is of very poor quality, but the sagittal T2 shows evidence of 30% fractures of T11 and T12 with increased signal in the upper plates. This is otherwise a non-diagnostic study. I cannot really make good determination as to changes in the T1 sequences from the axial series.

The patient was seen in follow-up on October 1, 2009. He reports continuing thoracic pain that does not radiate and low back pain of 7/10 that radiates to both legs. He is using Norco 10-325 every 4 hours, Flexeril 10 mg prn. He is prescribed Percocet 10-325 one every 4 hours #100. He is working light duty. He reports chest pain, sleep difficulty, numbness and tingling and feelings of anxiety and depression. The x-rays are reviewed and corroborate the fact that there are fractures at T11 and T12. Recommendation is for Kyphoplasty T11 and T12.

The provider's phone notes indicate three attempts to speak with a reviewer who had called.

Request for thoracic kyphoplasty at T11-12 was considered in review on October 7, 2009 with recommendation given for non-certification. The patient complained of back pain after a fall. MRI showed evidence of 30% fractures of T11 and T12 with increased signal in the upper plates. Rationale for non-certification states, a complete physical and neurologic examination was not submitted for review. There is no documentation of failure of conservative management including PT notes, adequate pain medication and bracing. Documentation of other pain generators such as a disc bulge was not completely ruled out.

Request for reconsideration for thoracic kyphoplasty at T11-12 was considered in review on October 20, 2009 with recommendation for non-certification. A peer discussion was realized. The patient is complaining of upper and lower back pain with radiation to the legs and arms. Independent radiographs/MRI are not available interpreted by a radiologist. Conservative treatment of medications and a TLSO brace were faxed by the provider. However, no MRI report is available. Other pain generators such as a disc bulge have not been completely ruled out. While it appears sufficient conservative care was provided, the official radiology reports were not submitted to establish medical necessity.

The patient was seen in follow-up on October 21, 2009. He reports burning pain in the thoracic spine with radiation into his abdomen and occasionally into both legs. With Percocet, his pain level is 7/10. His pain is increased with bending, increased activities and driving. He is neurologically intact. He is wearing a TLSO brace.

The provider submitted a letter of appeal dated October 29, 2009. The patient had a complete physical and neurological examination as noted on the initial evaluation report. Information regarding pain medication and bracing was also documented in the patient's medical records. Attempts were made to speak with the first line reviewer. The reviewer had copies of reports from the radiologist as well, and those are not mentioned in the review. A peer discussion was realized with the second level reviewer. It was stated that there were no reports from the radiologist. The insurance carrier has all of these records. The patient continues to suffer with severe pain. He has definite pathology and has received appropriate conservative therapy. A review of all the records is appropriate.

Request was made for an IRO.

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

Kyphoplasty is a minimally invasive spinal surgery procedure used to treat painful, progressive vertebral compression fractures. Kyphoplasty involves the use of a device called a balloon tamp to restore the height and shape of the vertebral body. This is followed by application of bone cement to strengthen the vertebra. Indications for kyphoplasty per ODG: (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 disk; (4) Affected vertebra is at least one third of its original height.

CT scan of approximately 90 days prior reveals, a very minimal anterior-superior compression fracture of the T11 vertebral body, involving the superior endplate, without evidence of posterior element involvement, malalignment or retropulsion. MRI of several months prior reveals, anterior compression fracture of the T11 vertebra with 10% loss of vertebral height; otherwise negative thoracic exam. Lumbar MRI impression noted a normal study.

The provider also took x-rays on September 16, 2009 which he has interpreted as: 30% fracture of T11. There is no other abnormality. A variation in the upper part of T12 is also seen in the signal change on the T1 images, compatible with a fracture at that level as well. The provider also performed an MRI on the same date which he interprets as: Very poor quality study, but the sagittal T2 shows evidence of 30% fractures of T11 and T12 with increased signal in the upper plates. This is otherwise a non-diagnostic study. I cannot really make good determination as to changes in the T1 sequences from the axial series.

The imaging studies as read by the independent radiologist notes only a 10% loss of vertebral height. Other pain generators have been ruled out by lumbar MRI. ODG requires loss of at least one third of the original height of the affected vertebra to warrant kyphoplasty.

Therefore, my recommendation is to agree with the previous non-certification for thoracic Kyphoplasty at T11-12.

The IRO's decision is consistent with the following guidelines:

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

The Official Disability Guidelines - Lumbar Chapter (11-13-2009) Kyphoplasty:

Under study based on recent higher quality studies of a similar procedure. (Kallmes, 2009) (Buchbinder, 2009) See Vertebroplasty. There may be highly selected patients who were outside the scope of the two high quality trials 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.)

Indications for Surgery - Kyphoplasty (while Under study in ODG)

- (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 disk;
- (4) Affected vertebra is at least one third of its original height. (Ledlie, 2006)