



**CLAIMS EVAL**

*Utilization Review and  
Peer Review Services*

Notice of Independent Review Decision-WC

**DATE OF REVIEW: 9-29-10**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

In office vertebroplasty at T8 at Pain Resources

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

American Board of Orthopaedic Surgery-Board Certified

**REVIEW OUTCOME**

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

- Upheld (Agree)
- Overturned (Disagree)
- 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**

- 6-9-10 MD., office visits on 6-9-10, 7-7-10 and 7-27-10.
- 6-11-10 MRI of the thoracic spine.
- 8-3-10 MD., office visits on 8-3-10 and 8-19-10.
- 8-12-10 Utilization Review.
- 9-10-10 Utilization Review.
- 9-17-10 MD., performed a Prospective Review.

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

MD., the claimant is a "male" that presents for evaluation of a back injury. In exam, the claimant has a normal gait. Range of motion of the cervical spine is normal and full. Range of motion of the lumbar spine shows decreased flexion with pain, decreased extension with pain, decreased left and right rotation with pain. Muscle strength is 5/5, muscle tone is normal. Neurological exam is normal. Impression: Fracture vertebrae thoracic unspecified - no cord and pain in the thoracic spine. Plan: MRI of the spinal canal contents. The claimant may return to work with restrictions. The claimant states that Vicodin and Aleve are causing stomach irritation. The claimant will start Celebrex, Ultram and Lidoderm for pain control. If there is a fracture, referral to pain management.

6-11-10 MRI of the thoracic spine shows a compression fracture of T8 with slight loss of height and with marrow edema compatible with recent compression. Slightly expanded right T10-T11 foramen and fluid signal within it compatible with a small root meningocele. There are similar lesions without expanded foramina on the left at T10-T11 and at T5-T6. Further evaluation with contrast enhanced study is recommended to rule out the possibility of neural tumor such as schwannoma.

Follow up with Dr. on 7-7-10 notes the claimant still has discomfort though improving pain. She has not seen pain management yet. The evaluator will try to refer again for consideration of vertebroplasty. The claimant will continue with Lidoderm patches since states those are helping with her pain. The claimant will continue with work restrictions.

Follow up with Dr. on 7-27-10 notes the claimant has not seen pain management yet. The claimant just returned from vacation and has heard from pain management and will make appointment. On exam, the claimant has normal cervical and lumbar range of

motion. Muscle strength is 5/5. Sensory exam is normal. Patellar reflexes are 2/4. The claimant is to return as needed. The claimant's pain is controlled with Lidoderm patches. She is to discuss options with pain management for any further treatment.

8-3-10 MD., the claimant is a female who works as an xx for xxxx. Patient was lifting a box of books on xx/xx/xx when she felt a significant pop in her mid thoracic back. Patient's pain was immediate in onset and severe. Pain has continued to be severe. She has undergone treatment with medication management, which has included a muscle relaxant and analgesic. She was treated with Valium at one point; however, she felt significant side effects from the Valium and discontinued use of that medication. She has had improvement with the use of Lidoderm patch over the thoracic spine region. Patient has continuation of pain with pain level 4-8 on a numeric pain scale, with 0 being no pain, 10 being the worst pain experienced. Initially, the pain radiated to the anterior then wall after injury. Pain has been localized into the mid thoracic region just below her shoulder blades. On exam, the claimant has normal symmetry of the cervical, thoracic, and lumbar spine. Exam of the cervical spine is unremarkable. At the thoracic spine, she has significant pain with flexion and extension of the thoracic spine is well as pain over the approximate T8 vertebral body just inferior to the scapula level. The claimant has normal exam of the lumbar spine. The claimant has normal neurologic findings of her upper and lower extremities. The evaluator recommended a thoracic T8 vertebroplasty. The procedure will be performed with the use C-arm fluoroscopy and intravenous sedation.

A Utilization Review dated 8-12-10 notes the requested service exceeds the Official Disability Guideline level of care. Based on the documentation submitted for review, plain x-rays demonstrated a compression fracture, confirmed by MRI. The degree of compression was described as slight with marrow edema and a small associated right paraspinal hematoma. The patient's treating physician, Dr. noted a normal neurologic exam and clinical improvement on his last note submitted. Dr. first saw the patient on xx/xx/xx at which time a brace was to be ordered. No physical therapy has been instituted. Based on ODG, the service requested is not indicated at this time. The patient warrants a trial of bracing and physical therapy. Physician Advisor attempted a peer to peer phone discussion with Dr. on 8-10-10 and 8-11-10. Spoke to who confirmed that the bracing had just been ordered and no physical therapy has been performed. Left a call back number for Dr. for a peer to peer discussion. Did not receive a return call.

Follow up with Dr. on 8-19-10 notes the claimant reports pain from the thoracic compression fracture of about 20%. The claimant reports continued pain in the mid thoracic region. On exam, the claimant has pain in the mid thoracic region approximating T8 vertebral body at midline. There is also pain noted over the left paraspinous musculature at the level of T8, which a trigger point area is indentified in the left thoracic paraspinous musculature. The request for T8 vertebroplasty was denied. Of note, in the denial letter, it states that no physical therapy was requested. The evaluator reported he was not quite clear on what physical therapy modalities are used to treat thoracic compression fractures. He recommended the claimant undergo a

trigger point injections for thoracic myofascial pain of which thoracic myofascial pain may be a candidate to undergo physical therapy. The evaluator will make that request as well. The claimant was prescribed with Lidoderm patch which she uses on a prn basis.

A Utilization Review dated 9-10-10 notes the requested service exceeds the Official Disability Guideline (ODG) level of care. Based on the documentation submitted for review, X-rays documented a compression confirmed by MRI on 6-11-10. The degree of compression was described as slight with marrow edema and small associated right paraspinal hematoma. The clinician, Dr., noted a normal neurologic examination and clinical improvement. The requesting clinician evaluated the claimant on 8-3-10 at which time a brace was being ordered. No physical therapy has been instituted. ODG indicates severe debilitating pain or loss of mobility (which cannot be corrected by medical therapy) is required to undergo this procedure. The claimant is not having excruciating pain. Her pain is managed with Lidoderm patch. For this claimant, this procedure is not clinically indicated as she does not have uncontrolled pain or delayed healing of the compression fracture, Physician Advisor attempted a peer to peer phone discussion with Dr. on 9-7-10 and 9-9-10. Spoke to who indicated Dr. does not do peer to peer phone discussions.

9-17-10 MD., performed a Prospective Review. It was her opinion that per the Spine Treatment Guidelines, treatment of a work related injury must be adequately documented and evaluated for effectiveness. Performed studies on this claimant had confirmed a compression fracture at T8. The provider has failed to institute conservative treatment. As stated by Physician Advisor, this procedure is not clinically indicated as she does not have uncontrolled pain or delayed healing of the compression fracture. Unfortunately, a peer to peer could be performed since apparently Dr. does not do peer to peer discussions. According to the ODG, the criteria for percutaneous vertebroplasty while not recommended is indicated in cases of severe debilitating pain or loss of mobility that cannot be relieved by correct medical therapy. As mentioned by the Physician Advisor, records do not reflect that the claimant meets the ODG criteria and completion of conservative treatment is still pending. Therefore, the medical necessity for three day in office vertebroplasty at T8 of the thoracic spine at Pain Resources as requested by Dr. is not substantiated at this time.

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

Review of the available medical records reflects the claimant has a T8 compression fracture that occurred in early. Claimant has pain but physical activities are not limited. Pain is controlled with lidoderm patches.

Recent evidence based medical literature has questioned the benefit of vertebroplasty when compared with placebo. Claimant does not meet the criteria for this procedure. Most compression fractures heal in 3-4 month time frame. It has been about three

months since the onset of symptoms. Therefore, the request for T8 vertebroplasty is not reasonable or medically indicated at this juncture.

**ODG-TWC, last update 9-8-10 Occupational Disorders of the Low Back – Vertebroplasty:**

Not recommended based on recent higher quality studies. See Recent research below. May be an option to treat multiple myeloma (MML) patients with nonosteoporotic vertebral compression fractures. (Erdem, 2010) This procedure had been recommended for patients with delayed healing of vertebral compression fractures. Percutaneous vertebroplasty (PV) is a treatment for relieving pain in patients complaining of severe back pain induced by osteoporotic or neoplastic compression fractures. The success rate may exceed 90% in noncomparative studies and the complication rate is lower than 1%. (Mathis, 2003) (Lieberman, 2003) (Garfin, 2002) A previous 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) Acute osteoporotic vertebral compression fracture management includes bracing, analgesics, and functional restoration, and patients with chronic pain beyond 2 months may be candidates for vertebral body augmentation, ie, vertebroplasty, according to this study. (Kim, 2006) Up to 80 percent of patients with pain unresponsive to correct medical treatment experience a significant degree of pain relief, and few serious complications have been reported. However, relatively few patients have undergone this procedure, and there are no data from controlled clinical trials or from studies with long-term follow-up. At the present time this procedure is still in the investigational stages, but may be appropriate for patients with no other reasonable options for medical treatment. (Levine, 2000) This study showed significantly fewer refractures after vertebroplasty in patients who engage in back-extensor-strengthening exercises. (Huntoon, 2008) (Kyphoplasty is a newer procedure, and some clinicians have concluded it is superior to vertebroplasty.)

Recent research: Two new high-quality clinical trials, the first randomized controlled studies of this procedure, have shown that control-group patients experienced similar improvements to those treated with vertebroplasty for osteoporotic vertebral fractures. The authors concluded that, in view of the known potential adverse effects and no benefit, vertebroplasty should not be used in clinical practice. These results have changed vertebroplasty from a procedure that is virtually always considered to be successful to one that is considered no better than placebo. Previous studies of vertebroplasty probably overestimated the treatment effect by failing to take into account the natural history of painful vertebral fractures, which tend to improve over time. While patients are often in excruciating pain and have no other options, and this

procedure is easy to do, augmentation should only be considered in a subset of patients, but new studies are necessary to identify who these patients might be. (Kallmes, 2009) (Buchbinder, 2009) There have been numerous examples of treatments that have looked promising in noncomparative studies but have subsequently been shown to be no better than placebo, a sham procedure, or standard care, including arthroscopy for osteoarthritis of the knee and high-energy shock-wave therapy for plantar fasciitis. Each of these looked promising early on, but didn't do well after rigorous study. There may be highly selected patients who were outside the scope of the two high quality trials above, who might still derive benefit from this procedure, for example, with three or more multiple simultaneous compression fractures despite bisphosphonate therapy, or pathologic fractures due to vertebral body neoplasms. (McGirt, 2009) Using vertebroplasty to treat multiple myeloma (MML) patients with nonosteoporotic vertebral compression fractures (VCF) reduces pain and disability. The recent news reports on the dangers of vertebroplasty has needlessly frightened millions of cancer sufferers who could have had vertebral augmentation to alleviate their pain. (Erdem, 2010) A recent technology assessment by the California Technology Assessment Forum (CTAF) recommended that vertebroplasty does not meet CTAF criteria for safety, effectiveness and improvement in health outcomes for the treatment of osteoporotic vertebral compression fractures. (Karlner2, 2010) A recent manufacturer-sponsored RCT without any blinding concluded that vertebroplasty is effective and safe in a selected subgroup of patients with acute (but not subacute or chronic) osteoporotic vertebral fractures and persistent pain (30 days until significant pain relief versus 116 days with conservative treatment). (Klazen, 2010) Criteria for percutaneous vertebroplasty (while Not recommended in ODG):

- o Severe debilitating pain or loss of mobility that cannot be relieved by correct medical therapy.
- o Other causes of pain, such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging.
- o The affected vertebra has not been extensively destroyed and is at least one third of its original height.

**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)