

## Notice of Independent Review Decision

**DATE OF REVIEW:**

11/16/2009

**IRO CASE #:****DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Osteoplasty T12 with one day length of stay.

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

Doctor of Osteopathy, Board Certified Anesthesiologist, Specializing in Pain Management

**REVIEW OUTCOME**

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

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.

**Osteoplasty T12 with one day length of stay is not medically necessary.**

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

- TDI/DIVISION OF WORKERS' COMPENSATION Referral form
- 11/09/09 letter
- 11/06/09 MCMC Referral
- 11/05/09 Notice to Utilization Review Agent of Assignment
- 11/05/09 Notice Of Assignment Of Independent Review Organization
- 11/05/09 Notice To MCMC, LLC Of Case Assignment
- 11/05/09 letter
- 11/05/09 Confirmation Of Receipt Of A Request For A Review, DWC
- 11/04/09 Request For A Review By An Independent Review Organization
- 10/07/09 Reconsideration/Appeal of Adverse Determination letter
- 10/06/09, 08/24/09 Followup notes, P.A., Back Institute
- 09/23/09 Billing Worksheet, Radiology
- 03/30/06 to 09/22/09 Followup notes, D.O., Back Institute
- 09/14/09 Utilization Review Determination letter
- 09/01/09 Surgery Scheduling Slip/Checklist
- 09/01/09 Periodic Outcomes Evaluation, Back Institute
- 08/21/09 CT lumbar spine, Surgical Hospital

- 08/17/09 ED Physician Note, M.D.
- 08/17/09 Admission Acknowledgements
- 07/31/09 NM TBBS report, Radiology Associates
- 04/21/09 Operative Report, D.O., Surgery Center
- 03/09/09 CT lumbar spine, Center for Diagnostics & Surgery
- 11/13/08, 06/08/06 Procedure Note, D.O., Physicians Surgical Center
- 03/10/08 Radiology Report (radiographs of spinal cord stimulator), P.A., Back Institute
- 02/26/08, 01/17/07, 01/16/07 Operative Notes, D.O., Medical Center
- 01/22/07 Followup note, P.A.-C., Back Institute
- 06/08/06 Procedure Note, D.O., Physicians Surgical Center
- 05/17/06, 04/17/06, 06/27/05 Followup notes, M.S., Back Institute
- 02/03/05 History and Physical, D.O., Back Institute
- 02/03/05 Radiology Review (radiographs of the lumbar spine), D.O., Back Institute
- Undated Insured Worker Information form, Back Institute
- ODG Integrated Treatment/Disability Duration Guidelines for Low Back – Lumbar & Thoracic (Acute & Chronic)

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

The injured individual is a female with date of injury xx/xxxx, history of lumbar fusion and spinal cord stimulator (SCS). She fell in xx/xxxx and hit her back on the bathtub. She went to the Emergency Room (ER) where a T12 compression fracture was suspected. Bone scan showed increased uptake. The CT dated 08/2009 examined only the lumbar spine and showed a herniation of nucleus pulposus (HNP) at L3/4. The injured individual has had a brace and medications for this. The attending provider is now suggesting osteoplasty.

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

This procedure has come under intense scrutiny in the literature lately and the consensus is that it works no better than placebo. In this injured individual's case, the CT did not evaluate the thoracic spine therefore it is not clear why Dr. 's Physician Assistant stated there was no thoracic bony fragment. Also, the CT showed a HNP at L3/4 which could be causing her pain. There is no radiographic indication that her T12 vertebra is intact at over one third of its height as required by Official Disability Guideline.

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

##### **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Not recommended based on recent higher quality studies. See Recent research below. 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)

Criteria for percutaneous vertebroplasty (while Not recommended in ODG):

Severe debilitating pain or loss of mobility that cannot be relieved by correct medical therapy. Other causes of pain, such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging.

The affected vertebra has not been extensively destroyed and is at least one third of its original height.