



MedHealth Review, Inc.

661 E. Main Street
Suite 200-305
Midlothian, TX 76065
Ph 972-921-9094
Fax (972) 827-3707

Notice of Independent Review Decision

DATE NOTICE SENT TO ALL PARTIES: 10/28/13

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of an OP lumbar vertebralplasty at L3 22521 (PNR 77002) with 23 hour stay.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of an OP lumbar vertebralplasty at L3 22521 (PNR 77002) with 23 hour stay.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed: 1/29/13 to 8/22/13 notes, 7/16/13 to 8/15/13 outcomes assessment reports, 7/16/13 pt self-assessment report, 5/7/13 to 7/1/13 orders notes, 5/28/13 note, 5/28/13 denial letter, 5/15/13 lumbar MRI

report, 1/21/13 lumbar CT report, 1/24/13 email, 10/16/12 care now report, various DWC 73 reports, office notes 1/15/13 to 1/23/13, 1/14/13 notes from, 1/15/13 incident details report, and 1/15/13 x-ray report.

9/20/13 denial letter, 8/21/13 denial letter, DWC 32 report, 7/19/13 DD report, and 2/15/13 request for information.

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The worker experienced severe low back pain. The pain has persisted despite medications, restricted activities, bracing and therapy. Exam findings from August 2013 have included lumbar para-spinal tenderness over L3, along with reduced lumbar motion. A lumbar MRI from 5-13 revealed a superior end plate compression fracture at L3. Denial letters documented the lack of provision of detailed non-operative treatment and the lack of support for the request in the recent literature.

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

Despite the persistent subjective and objective findings and the reported failure of medications, bracing in therapy; the most recent literature does NOT support a benefit of the requested procedure over and above that of control-group patients/placebo. Therefore the request does not appear to be medically necessary in this patient with a superior end plate compression fracture. This is partially also due to the relative lack of significant vertebral height reduction and the potential for additional improvement over time. Applicable ODG criteria referenced below does not support the requested procedure as being medically reasonable or necessary at this time.

Reference: ODG Low Back-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. 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. 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. 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. 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). The AAOS made a strong recommendation against vertebroplasty for treatment of spinal compression fractures, saying there is very strong Level 1 evidence to suggest that vertebroplasty does not provide the types of benefits that it was previously thought to provide. 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. The recent AAOS guideline on spinal compression fractures recommends against vertebroplasty based on strong evidence. Vertebroplasty does not meet California Technology Assessment Forum criteria for effectiveness. Individual patient data meta-analysis from two blinded trials of vertebroplasty, powered for subgroup analyses, failed to show an advantage of vertebroplasty over placebo for participants with recent onset fracture or severe pain. These results do not support the hypothesis that selected subgroups would benefit from vertebroplasty. Plus, at one month those in the vertebroplasty group were more likely to be using opioids.

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)