

Notice of Independent Review Decision

**DATE OF REVIEW:** 10/25/2010

**IRO CASE #:**

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

Medical necessity for cold therapy machine between 9/8/10 to 11/7/10, bone stimulator and TLSO

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

The physician performing this review is a licensed, practicing Orthopedic Surgeon. He is Board Certified, American Board of Orthopedic Surgery. He is a member of his local, state, and national medical associations. He has co-authored several publications. He has been in practice since 1992.

**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.

A cold therapy cannot be approved from 09/08/10 through 11/07/10 based on its frequency and duration. They are typically used for the acute period after surgery.

A bone growth stimulator is recommended. The claimant underwent a two-level procedure from L4 to S1, a two-level fusion. This would meet the requirements

based on Official Disability Guidelines for the use of a bone growth stimulator. The claimant has a history of smoking.

A TLSO could be used postoperatively. Official Disability Guidelines are somewhat inconclusive stating that they are under study. Custom braces are not approved, but a standard thoracolumbosacral orthosis (TLSO brace) could be approved postoperatively for comfort and immobilization. Case by case recommendations are necessary. The claimant could have a standard thoracolumbosacral orthosis (TLSO brace). It was noted that she is a smoker, and they are using a bone stimulator. Thus, I would approve the thoracolumbosacral orthosis (TLSO brace).

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records Received: 14 page fax 10/13/10 Texas Department of Insurance IRO request, 58 page fax 10/13/10 Provider response with with administrative and medical records, 36 page fax 10/13/10 URA Response to disputed services with administrative and medical records

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

This is a male claimant with a history of low back pain and bilateral lower extremity pain and diagnosed with lumbar radiculopathy, lumbago and status post lumbar discectomy surgery. The claimant subsequently underwent a transforaminal lumbar interbody fusion L5-S1 and L4-5 re-do hemilaminectomy, right L4-5 hemilaminectomy and redo left L5- S1 hemilaminectomy on 09/02/10. A physician letter dated 09/02/10 noted the claimant post lumbar fusion with fixation not optimal secondary to significant osteoporosis and the claimant with a history of smoking. A lumbar brace was recommended along with a bone stimulator due to the multilevel fusion. A cold therapy machine was also recommended to reduce pain and swelling.

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

Official Disability Guidelines Treatment in Worker's Comp 2010 Updates, Low Back :

Cryotherapy: Cold/heat packs:

Recommended as an option for acute pain. At-home local applications of cold packs in first few days of acute complaint; thereafter, applications of heat packs or cold packs. ([Bigos, 1999](#)) ([Airaksinen, 2003](#)) ([Bleakley, 2004](#)) ([Hubbard, 2004](#)) Continuous low-level heat wrap therapy is superior to both acetaminophen and ibuprofen for treating low back pain. ([Nadler 2003](#)) The evidence for the

application of cold treatment to low-back pain is more limited than heat therapy, with only three poor quality studies located that support its use, but studies confirm that it may be a low risk low cost option. ([French-Cochrane, 2006](#)) There is minimal evidence supporting the use of cold therapy, but heat therapy has been found to be helpful for pain reduction and return to normal function.

## Bone growth stimulators (BGS)

Under study.

Criteria for use for invasive or non-invasive electrical bone growth stimulators:

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion:

- (1) One or more previous failed spinal fusion(s);
- (2) Grade III or worse spondylolisthesis;
- 3) Fusion to be performed at more than one level;
- (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); (5) Diabetes, Renal disease, Alcoholism; or
- (6) Significant osteoporosis which has been demonstrated on radiographs.

## TLSO

Back brace, post operative (fusion)

Under study, but given the lack of evidence supporting the use of these devices, a standard brace would be preferred over a custom post-op brace, if any, depending on the experience and expertise of the treating physician. There is conflicting evidence, so case by case recommendations are necessary (few studies though lack of harm and standard of care). There is no scientific information on the benefit of bracing for improving fusion rates or clinical outcomes following instrumented lumbar fusion for degenerative disease.

Although there is a lack of data on outcomes, there may be a tradition in spine surgery of using a brace post-fusion, but this tradition may be based on logic that antedated internal fixation, which now makes the use of a brace questionable. For long bone fractures prolonged immobilization may result in debilitation and stiffness; if the same principles apply to uncomplicated spinal fusion with instrumentation, it may be that the immobilization is actually harmful. Mobilization after instrumented fusion is logically better for health of adjacent segments, and routine use of back braces is harmful to this principle. There may be special circumstances (multilevel cervical fusion, thoracolumbar unstable fusion, non-instrumented fusion, mid-lumbar fractures, etc.) in which some external immobilization might be desirable

**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)