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**Notice of Independent Review Decision**

**DATE OF REVIEW:** 9/8/10

**IRO CASE #:**

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

The item in dispute is the prospective medical necessity of a lumbar TLS back brace.

**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 Physical Medicine and Rehabilitation with a subspecialty in Pain Management. 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 a lumbar TLS back brace.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties:  
Pain Management & Anesthesiology and

These records consist of the following (duplicate records are only listed from one source): Records reviewed from Pain Management & Anesthesiology: MD letter – 8/11/10, Operative Report – 8/10/10, Medical Necessity letter – 7/21/10; A. Spurrier letter – 8/23/10; and Soft Spinal System / Orthomerica brace info. Records reviewed from: Denial letter – 8/6/10 & 8/18/10; MD letter of medical necessity – 7/21/10, Post Procedure Follow-up Check-list – 7/21/10 & 8/10/10, Progress Note – 7/12/10 & 7/21/10, Lumbar Myelogram report – 7/21/10, Script for Post Myelogram CT – 7/12/10, Procedure Note – 7/12/10, Urine Toxicology report – 7/12/10, Letter of Medical Necessity – 8/12/10; A. letter – 8/18/10.

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

**PATIENT CLINICAL HISTORY (SUMMARY):**

This patient was injured on xx/xx/xx. She underwent an intrathecal catheterization on 8/10/10 secondary to a dislodged catheter. MD ordered a TLSO for post-procedural care. This was denied by the insurance carrier's peer review process.

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

The ODG notes that a lumbar orthosis is not recommended for prevention of LBP. Under study for treatment of nonspecific LBP. Recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, or post-operative treatment. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. Lumbar supports do not prevent LBP. Among with previous low back pain, adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism. 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, i.e., vertebroplasty. An RCT to evaluate the effects of an elastic lumbar belt on functional capacity and pain intensity in low back pain treatment, found an improvement in physical restoration compared to control and decreased pharmacologic consumption. A systematic review on preventing episodes of back problems found strong, consistent evidence that exercise interventions are effective, and other interventions not effective, including stress management, shoe inserts, back supports, ergonomic/back education, and reduced lifting programs. See also Back brace, post operative (fusion).

Back brace-post operative- 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.

The reviewer indicates the requestor is requesting the TLSO to “support the catheter to prevent future dislodgment and spinal fluid leak.” The treating doctor does not quote any sources to support this request. As per above, the ODG does not support the use of a TLSO in the requested manner. According to Krakovsky et al. Complications associated with intrathecal pump delivery: a retrospective evaluation, AJPM Vol 17, No. 1, Jan 2007, the only mention of an abdominal binder is indicated in the case of a spinal hygroma.

The reviewer notes that despite searching literature, he could not find any mention of the requested orthosis being used in a similar fashion after implantation of an intrathecal delivery system. Therefore, the requested service is found to be not medically necessary at this time.

**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) Krakovsky et al. Complications associated with intrathecal pump delivery: a retrospective evaluation, AJPM Vol 17, No. 1, Jan 2007,
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)