



Specialty Independent Review Organization
Notice of Independent Review Decision

DATE OF REVIEW: 08/25/10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of a lumbosacral orthosis Deroyal Ultralign Back brace between 7/29/10 and 9/27/10.

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 disagrees with the previous adverse determination regarding the prospective medical necessity of a lumbosacral orthosis Deroyal Ultralign Back brace between 7/29/10 and 9/27/10.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:, MD and Inc.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from Dr.: 7/27/10 lumbar x-ray report, office notes by orthopedic 7/15/10, 7/28/10 letter by Dr. and 7/27/10 operative report.

: ODG guideline summary, surgical DME order 7/16/10, office notes by 5/29/09 to 7/15/10, 7/15/10 hospital routing form, 6/9/09 and 10/13/09 operative reports, WC verification form 7/1/10, 7/11/10 surgical scheduling form, patient profile form, 5/11/10 myelogram and CT lumbar report, 4/9/10 lumbar MRI report, 3/9/10 ESI report, 5/26/09 lumbar MRI report, 8/3/10 denial letter and physician report, 7/27/10 denial letter & physician report and 7/16/10 DME order.

A copy of the ODG was provided by the Carrier/URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant was status post left-sided L5-S1 decompression and partial discectomy on 10/13/09. The claimant complains of recurrent low back pain with radiation, along with exam findings denoting tenderness, spasm, a positive SLR and absent reflexes. The claimant has been considered for a bilateral decompression and discectomy (along with instrumented fusion) at the same level, along with a custom back brace post-op. Denial letters reveal a rationale of a lack of evidence of the claimant's outcome post-op. The 7/27/10 operative summary and the 7/28/10 dated letter of medical necessity were reviewed, revealing the "radical excision" performed, along with an indication for a back brace.

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

The claimant has undergone a very significant decompression and then instrumented fusion. To decrease the potential for significant extremes of lumbar spinal motion, and, for purposes of pain control associated with the highly intensive/invasive procedure, a spinal orthosis is reasonably required as per applicable guidelines. A custom brace is reasonably required due to the swelling at the large incisional area associated with the highly invasive spinal operative procedure and to allow for a lack of compromise of abdominal and thoracic functionality. The situation falls under the special circumstance in which this multiple-operated spine has been extensively decompressed and (despite fusion) has a medical reasonable requirement for optimal stabilization via adjunctive support with a custom-fit brace that contours to this individual with altered post-op soft tissue anatomy.

ODG: 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 states that this case is one of the

“special circumstances” in their opinion; therefore, the custom brace is medically necessary.

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)