



**DATE OF REVIEW:** 5/14/07

**MDR TRACKING #:**

**NAME:**

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

Determine the medical necessity for the previously denied total disk replacement at L5-S1 with 3 days length of stay.

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

Texas licensed Surgeon.

**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)

[Check only one of the boxes above.]

Previously denied total disk replacement at L5-S1 with 3 days length of stay.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

1. UM Nurse Summary, undated
2. Lumbar spine MRI, 07/11/06
3. EMG/NCS, 09/22/06
4. Discogram, 02/16/07
5. Office note, 03/20/07
6. Peer review, 03/26/07 and 04/24/07
7. Letter of Medical Necessity, 04/13/07
8. Request for IRO, 04/03/07

### **INJURED EMPLOYEE CLINICAL HISTORY [SUMMARY]:**

**Patient's age:** xx  
**Gender:** Male  
**Date of Injury:** xx/xx/xx  
**Mechanism of injury:** Fall type injury.  
**Diagnoses:** Low back pain; mild spondylosis; lumbar disc herniation at L1-2.

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

The claimant continued to have ongoing low back pain since a fall. An MRI, dated xx/xx/xx, demonstrated multiple levels of lumbar spondylosis, annular tear at L1-2 and disc bulge with annular tear at L5-S1. A discogram and CT, dated 2/16/07, reported concordant pain at L5-S1 with small annular tears at L1-2 and L4-5 without reproduction of pain. The records reviewed indicated that the claimant failed a full course of conservative treatment. Clinical findings noted motor weakness in the right lower extremity. Electrodiagnostic studies, dated 9/22/06, showed no evidence of radiculopathy or peripheral polyneuropathy. The impression was internal disc disruption with continued axial low back pain. Total disc replacement at L5-S1 was proposed. This request was not approved on two separate occasions by the claimant's insurance carrier. This reviewer agrees with the previous determinations. The use of artificial disc replacement remains investigational. There is FDA literature that specifically states that although this is approved for safe use, further investigation is necessary. The body of literature continues to grow regarding these disc implants; however, a number of questions remain. The longevity of these implants is unknown. The effect of deterioration of the implant material is unknown. The effect of the implants on adjacent levels is unknown. As such, it would be this reviewer's opinion that the artificial disc, while FDA approved for use at one level, remains investigational as outlined in the FDA language. It has not yet been proven effective for long-term pain relief. The long-term beneficial results versus long-term risks are still unknown, and additional long-term study is needed. In addition, the Official Disabilities Guidelines do not recommend total disc replacement at this time. Return To Work Guidelines (2007 Official Disability Guidelines, 12th edition) Integrated with Treatment Guidelines (ODG Treatment in Workers' Comp, 5th edition, Low back, updated 5/07) Not recommended at this time for either degenerative disc disease or mechanical low back pain. While disc replacement, as a strategy for treating degenerative disc disease, has gained substantial attention, it is not currently possible to draw any conclusions concerning disc replacement's effect on improving patient outcomes. The studies quoted above have failed to demonstrate a superiority of disc replacement over simple fusion for the limited indications for surgical treatment of lower back pain. Thus disc replacement is considered a controversial and unproven alternative to fusion surgery. Note: On 8/14/06, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine

**If applicable this section should include the following:**

- Specific basis for divergence from the Division of Workers' Compensation (DWC) policies or guidelines adopted under Labor Code §143.011.

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

[Check any of the following that were used in the course of this review.]

- 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 CHRIOPRACTIC QUALITY ASSURANCE AND 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).

**CompPartners, Inc. hereby certifies that the reviewing physician or provider has certified that no known conflicts of interest exist between that provider and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent, or any of the treating doctors or insurance carrier health care providers who reviewed the case for the decision before the referral to CompPartners, Inc.**