

# I-Decisions Inc.

An Independent Review Organization  
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## NOTICE OF INDEPENDENT REVIEW DECISION

**DATE OF REVIEW:**

Jan/21/2010

**IRO CASE #:**

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

ARTIFICIAL DISK REPLACEMENT @ L4-5, L5-S1 W/2 DAY LOS

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

M.D., Board Certified Orthopedic 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)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

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

Dr. office notes 05/24/02, 06/07/02, 10/02/02, 11/08/02, 09/08/09, 11/03/09

MRI lumbar 06/04/02

X-ray 09/08/09

MRI lumbar 10/07/09

Dr. ( spine ) / letter 11/11/09

Pain management evaluation 11/24/09

Denial Notices/Peer reviews 12/03/09, 12/21/09

**PATIENT CLINICAL HISTORY SUMMARY**

This is a male with a reported history of lower back pain which was related to disc changes at L4-5 and L5- S1. The records indicated the claimant with progressively worsening mechanical back pain and failed conservative treatment. The claimant was noted to have internal disk derangement L4-5 and L5-S1 with MRI changes that showed height hydration and small posterior annular bulges. The treating physician deemed the claimant was an excellent candidate for a two level arthroplasty and recommended a two level Pro disc lumbar disc replacement at both the L4- 5 and L5- S1 levels.

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

The ODG clearly recommends against artificial disc replacement in the lumbar region. Furthermore, the application at two different levels would appear to be beyond that which is outlined in the initial FDA approval for marketing. The reviewer is unable to recommend this procedure as medically necessary based on those factors. The reviewer finds that medical necessity does not exist for Artificial Disk Replacement @ L4-5, L5-S1 w/2 day LOS.

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

prosthesis

Not recommended in the lumbar spine, but under study in the cervical spine, with recent promising cervical results

Other than spinal fusion, there are currently no direct comparison studies, and artificial disc outcomes in the lumbar spine are about the same as lumbar fusion, but neither results have demonstrated superiority compared with recommended treatments, including nonoperative care.

While there is an increasing interest in spinal arthroplasty as an alternative to fusion in conjunction with cervical discectomy, the longevity of this new procedure is unknown, and data on both mechanical failure and aseptic loosening are yet to be determined. The result of this study suggests that there is sufficient bone ingrowth on the coated surface of the Bryan prosthesis endplates to securely stabilize the prosthesis.

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.

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

ACOEM-AMERICA 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)

