

I-Decisions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW: OCTOBER 18, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

ProDisc replacement, two levels, L4/L5 and L5/S1 with two days of inpatient stay.

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

MD, 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)

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.

The reviewer finds that medical necessity does not exist for ProDisc replacement, two levels, L4/L5 and L5/S1 with two days of inpatient stay.

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx-year-old male. He has had multiple problems in the past. His original work injury was in xxxx when he had a back injury. He underwent a two-level laminectomy in the lumbar spine, which apparently was decompressive.

However, there is note in one report of a potential fusion at these levels. He apparently got better after this operation and went back to work and was then re-injured again when lifting an object in xx/xx. He initially had an MRI scan performed, which did not reveal causes for radiculopathy. Indeed, he did not complain of radiculopathy. However, sometime later, he developed right-sided sciatica. Another MRI scan was performed in September 2008, which revealed causes for this sciatica. He has a pertinent previous history for an L2 fracture. The MRI scans have conflicting information as in the medical record as to the fusion levels. The first MRI scan states that he has a fusion posteriorly

from T12, and another imaging study in September 2008 notes abnormal-appearing posterior elements at L1/L2. Dr. [redacted] in his notes indicates that the patient has had a fusion from L1 to L3 posteriorly. He also fractured his skull and had reconstruction of that and ended up in 2000 with a hip replacement for posttraumatic degenerative arthritis of the right hip. A suggestion of partial arthroplasty at two levels has been made due to his previous fusion. While the medical records indicate that anterior approach with arthroplasty is preferable due to his possible previous fusion superiorly, the records do not substantiate why this patient should undergo this procedure that deviates so significantly from the FDA Guidelines, as it is well known that disc collapse, multiple levels., etc., are considered contraindications to this procedure. From the ODG Guidelines and FDA Guidelines, there is no support for the use of the ProDisc in this particular indication. The previous reviewer indicated a decompression would be indicated in this patient for his sciatica.

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

Due to the issues from the ODG Guidelines and the FDA recommendations for artificial disc replacement in conjunction with the previous fusion, this particular reviewer would concur that neither fusion nor a ProDisc replacement would be recommended based upon the lack of evidence-based outcomes studies at this time. It is for this reason that the medical necessity has not been found in this case for the indicated procedure, and the previous adverse determination is upheld. The reviewer finds that medical necessity does not exist for ProDisc replacement, two levels, L4/L5 and L5/S1 with two days of inpatient stay.

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)