

SENT VIA EMAIL OR FAX ON
Jul/02/2009

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An Independent Review Organization

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DATE OF REVIEW:

Jul/01/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

L2/3 total disc replacement prodisc

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

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

OD Guidelines

Operative report procedure 11/08/07

Office notes Dr. 01/15/08, 04/14/08, 07/07/08, 10/01/08, 01/05/09, 05/19/09

Office notes Dr. 04/14/08, 06/09/09, 06/23/08, 10/01/08, 01/05/09, 05/19/09

Operative report 05/14/08

MRI 06/20/08

Office note Dr. 07/07/08

Operative report 08/19/08

X-rays 10/01/08

COPE program, Cleared for discography 02/05/09

Office note 03/27/09

Discogram 05/06/09

Peer review 06/02/09

Peer review 06/05/09

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a male with a history of back and leg pain following an unknown injury on xx-xx-xx. The claimant underwent artificial disc replacement at L4-5 and anterior lumbar interbody fusion with instrumentation at L5-S1, surgery date not provided, and continued with pain. Dr. Dr. and Dr. followed the claimant for treatment that included narcotic pain medication, chiropractic therapy, and injections. The claimant underwent a rhizotomy at L4-L5 on 11/08/07 with reported relief. On 05/14/08, facet medial branch block bilaterally at L4-5 was performed with only two days of pain relief.

An office visit on 06/09/08 noted complaints of pain and numbness in the right calf to the

dorsum of the right foot and inability to dorsiflex the right foot. MRI on 06/20/08 noted the disc prosthesis at L4-5, bone graft with stabilizing screws at L5-S1 and findings consistent with an annular tear of the posterior L2-3 disc margin with a three to four millimeter central to right paracentral disc protrusion with moderate disc degeneration. Repeat rhizotomy at L4 and L5 was done on 08/19/08.

The claimant continued with chronic, intractable lower back and leg pain. X-rays noted the fusion well healed with no evidence of instability on dynamic views. A lumbar discogram on 05/06/09 reported concordant pain at L2-3 with a grade four posterior annular tear with disc bulge, some thecal sac effacement, and foraminal narrowing noted on CT. L1-2, and L3-4 levels were negative for pain. Right leg pain persisted with no evidence of neurovascular deficits on examination. Total disc replacement using the ProDisc prosthesis at L2-3 was requested.

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

The request for a total disc replacement at L2-3 in this particular case cannot be recommended as reasonable or medically necessary. The evidence-based literature does not support the use of this particular device based on failure of well-controlled clinical studies to compare it with other conservative measures. In general, studies have used arthrodesis as a comparison treatment, which has not historically resulted in uniform success. For the above stated reasons, the request can neither be viewed as reasonable or medically necessary.

Of note, the provisional FDA approval in this particular case was recommended for only L4-5 and L5-S1. The approval was provisional and required further investigation which suggests that this particular device remains investigational. There was no indication that this device would be approved for use in the L2-3 level.

In addition, in this particular case, this individual has had chronic intractable back pain following a two-level fusion. It is difficult to suggest further surgery in an individual who has been suffering from chronic back pain following previous surgeries. It is unlikely, **based on a careful review of all medical records**, that addition surgery is going to offer this gentleman any meaningful improvement regardless of the procedure of choice.

Official Disability Guidelines Treatment in Worker's Comp, 14th edition, Low back, Disc Arthroplasty

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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)