

P-IRO Inc.

An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW: APRIL 21, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Prodisc replacement C5/6 with two day length of stay

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

Doctor of Medicine (M.D.)
Board Certified in Orthopaedic Surgery

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
Literature No Date
Back Institute 10/07 thru 3/08
Spine Specialist 5/7/07
MRI 12/5/07
DC C Spine 4/11/07
Injection Eval 5/23/07
Services 12/17/07
PTS 7/25/07
4/07 thru 8/07

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is one year out from an injury to the cervical spine. He has neck pain and a C6 radiculopathy that has not responded well to excellent conservative care. The patient would like to proceed with a disc arthroplasty instead of ACDF after discussing the pros and cons of both. This has been denied by the insurance company due to the experimental nature of the procedure.

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

ODG criteria do not recommend cervical disk arthroplasty at this time. However, the ODG states that early results (24 month follow-up) in one study show better results than ACDF. This patient understands the experimental nature of the procedure. The patient is a surgical candidate and should be allowed to proceed with the requested procedure.

Disc prosthesis	<p>Not recommended. Given the extremely low level of evidence available for artificial disc replacement, it is recommended that this procedure be regarded as experimental at this time. (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) There may be more promise in the cervical spine than in the lumbar spine. At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement, whereas cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. (McAfee, 2004) 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. (Lind, 2007) The cervical spine disc prosthesis preserves cervical spine segmental motion within the first 6 months after surgery, but motion decreased over time after either disc prosthesis or anterior cervical discectomy and fusion (ACDF). (Nabhan, 2007) The U.S. Medicare insurance program said on May 28, 2007 in a draft proposal that it was rejecting coverage of artificial spinal disc replacement surgery no matter which disc was used. (CMS, 2007) On July 16, 2007 the FDA approved the Prestige® Cervical Disc System from Medtronic Sofamor Danek. (FDA, 2007) This study demonstrates the favorable outcomes of cervical disc arthroplasty using the Bryan disc in comparison to the gold standard, Anterior cervical discectomy and fusion (ACDF), at 24 months. Intermediate and long-term data collection will ultimately determine the feasibility of this device. (Sasso, 2007) See also the Low Back Chapter.</p>
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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)**