Applied Resolutions LLC

An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW: September 3, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Inpatient surgery for cervical disc/displacement

A 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
Office note, Dr. , 2/22/08
MRI, 3/4/08 MRI
Office note, Dr. , 3/13/08
Procedure note, 4/30/08
Office note, 5/2/08, 06/27/08, 07/07/08
Cervical ESI, 6/4/08
Peer review, 7/29/08, 08/13/08
Appeal letter, 8/13/08

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant is a xx-year-old male employed in the who sustained a neck injury on xx/xx/xx. MRI on 03/04/08 noted multilevel cervical spondylosis and a small central disc protrusion with mild spinal canal stenosis and mild bilateral neuroforaminal narrowing at C4-5, C5-6 and moderate left foraminal narrowing at C3-4. Treatment included oral

steroids, activity modification, therapy and cervical epidural steroid injections. The claimant continued with pain and limited cervical motion. Surgery was proposed with discectomy and disc arthroplasty at C4 and C5. The requested procedure was non-certified on two separate reviews. The request was submitted for medical dispute resolution.

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

This relatively young claimant has multilevel degenerative disc changes. Disc replacement at one level certainly would not take into account the other degenerative levels. The basis for this person's discomfort is not clearly defined at one individual level. When one turns to accepted guidelines, the ODG guidelines outline that given the extremely low level of evidence available; the procedure is regarded as essentially experimental. Although it has been approved by the FDA, long term data is needed to suggest that these treatments are somehow superior. In fact, the early results from trials outline that 1 and 2 year outcomes for radicular symptoms are similar to the outcomes for traditional anterior cervical fusion surgery.

In short, the Reviewer would not recommend as medically necessary the proposed cervical replacement.

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates, Neck and Upper Back, Disc Prosthesis

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) Early results from trials of cervical disc arthroplasty appear to show 1- to 2-year outcomes for radicular symptoms that are similar to outcomes for anterior fusion surgery. There is no evidence to support the use of cervical disc arthroplasty in patients with neck pain who do not have primary radicular pain.

R. Douglas Orr, Paul D. Postak, Mircea Rosca, and A. Seth Greenwald. The Current State of Cervical and Lumbar Spinal Disc Arthroplasty J. Bone Joint Surg. Am., Oct 2007; 89: 70 - 75.

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**
  - R. Douglas Orr, Paul D. Postak, Mircea Rosca, and A. Seth Greenwald. The Current State of Cervical and Lumbar Spinal Disc Arthroplasty J. Bone Joint Surg. Am., Oct 2007; 89: 70 - 75.
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**