

P-IRO Inc.

An Independent Review Organization
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IRO REVIEWER REPORT TEMPLATE -WC

DATE OF REVIEW: OCTOBER 22, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Neck spine disc surgery

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

Cervical spine MRI, 05/21/07
Claimant information, 06/08/07
Office note, Dr. 06/08/07
Cervical epidural steroid injection, 06/25/07
CT myelogram, 08/17/07
Denial letter, 09/17/07 and 09/28/07
Request for appeal letter, Dr., 10/04/07
Department of Health and Human Services information provided
No ODG Guidelines

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male who was in a motor vehicle accident. Medical records pertaining to evaluation and treatment following the injury were not provided. The MRI of the cervical

spine on 05/21/07 showed a one centimeter cyst or hematoma in between the left C6 paraspinal muscles, disc bulges at the C2-3 through C7-T1 levels, moderate to severe narrowing at right C3-4, right C5-6 and bilateral C6-7 foramina, moderate narrowing of right C6-T1 foramina, moderate narrowing on right to C7-T1 foramina and moderate spinal stenosis at C6-7 level.

Dr. saw the claimant on 06/08/07 for complaints of neck and left arm pain. Physical examination revealed that the etiology of his radiculopathy was the C6-7 level with pain down into his left trapezius and left arm. Spurling's sign on the left was positive. Flexion and extension x-rays that day showed no fracture. Grip strength on the left was 4/5 and biceps and triceps strength was 4/5. Impression was cervical radiculopathy with disc protrusion at C6-7. On 08/03/07, Dr. recommended a CT myelogram.

The CT myelogram on 08/17/07 showed left lateral formation at C6-7 level which caused severe left neural foramina stenosis and disc material could not be entirely excluded. Dr. authored a 10/04/07 appeal letter noting that the Prestige Disc was superior statistically to anterior cervical discectomy and fusion.

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

This claimant has cervical degenerative disc disease and cervical disc replacement has been recommended. Certainly there is some support for these procedures and FDA has determined that the procedure is safe for now. However, there is no long term data to determine the ultimate affect of the artificial implant. There is simply not enough literature available to prove that this procedure would be more beneficial in the treatment of single level degenerative disc change than the traditional procedure such as anterior cervical discectomy with fusion. Although some studies show that there has preservation of cervical spine motion within the first six months after the surgery, those same studies have shown that motion decreases over time. In this respect, and therefore the prosthesis and the one level fusion are quite similar. Although there is increasing interest in this type of treatment as an alternative to fusion, the data on failure including loosening and mechanical failure has yet to be gathered. The Reviewer would not consider this to be a more beneficial treatment for this person's medical condition. Therefore, the Prestige artificial disc replacement is not recommended as medically necessary.

Official Disability Guidelines Treatment in Workers' Comp 2007 Updates, Cervical Guidelines referred to use Low back Guidelines for disc prosthesis

Tropiano P, Huang RC, Girardi FP, Cammisa FP, Marnay T: Lumbar Total Disc Replacement: Seven to Eleven Year Follow-Up. The Journal of Bone and Joint Surgery, Volume 87-A, Number 3, March 2005

Boden, Scott, Balderston, Richard et al. Disc Replacements: This Time Will We Really Cure Low Back and Neck Pain? JBJS 86:411-422 (2004).

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
 - PLEASE SEE ABOVE