

Notice of Independent Review Decision

DATE OF REVIEW:

08/22/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Cervical Disc Replacement C3/C4

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

Board Certified Orthopaedic Surgeon

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

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 requested cervical disc replacement C3/C4 is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 08/15/08 MCMC Referral
- 08/14/08 Notice To Utilization Review Agent of Assignment,
- 08/14/08 Notice To MCMC, LLC Of Case Assignment,
- 08/14/08 Confirmation Of Receipt Of A Request For A Review, DWC
- 08/01/08 Request For A Review By An Independent Review Organization
- 07/29/08 letter from M.D.,
- 07/22/08, 07/10/08 Facsimile Transmission with notes, Orthopedics & Sports Medicine
- 07/18/08 letter from M.D
- 06/20/08, 05/21/08, 04/18/08, 02/29/08, 12/12/07, 11/14/07, 10/08/07 Progress Notes, M.D., Orthopedics & Sports Medicine
- 04/30/08, 02/13/08 Fax Transmittal Sheets with notes, M.D.,
- 04/22/08, 02/11/08 office notes, M.D.,
- 04/18/08 patient information sheet
- 01/31/08 History and Physical for Cervical Myelogram, M.D.
- 01/31/08 cervical myelogram, M.D.
- 01/31/08 Post Myelogram CT of the cervical spine, M.D.
- 01/10/08 Facsimile Transmittal Sheet with note, Radiology Center

- 01/07/08 Authorization for Release of Information
- 12/05/07 EMG/NCV report, Orthopedics and Sports Medicine
- 03/16/07 patient information sheet, Orthopedics & Sports Medicine
- Workers' Compensation Authorization/Visit Info (Precert form written on bottom, date not visible – poor copy)
- Copy of form with “Precert” written at bottom (poor quality copy)
- Undated Surgery Orders,
- Undated Exam Requisition Form, Radiology Center
- Note: Carrier did not supply ODG Guidelines.

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a female who was reported to have sustained a work-related injury on xx/xx/xx. The described mechanism of injury was a fall backwards injuring her neck. The initial treatment record and subsequent C5-C7 cervical fusion records are not in the reviewed material. She by report underwent a two level cervical fusion from C5-C7 in 03/2006. The first treatment record was dated 10/8/2007 to M.D. Dr. noted continuing neck complaints now mainly left-sided. He recommended an MRI with gadolinium. The MRI was reported to be non-conclusive secondary to artifact in his note of 11/14/2007. The MRI was done in an open magnet probably because of the injured individual's morbid obesity (5'4"-298 pounds), but was not a good study. M.D. performed electromyogram/nerve conduction velocity study (EMG/NCV) on 12/05/2007. It revealed mild left carpal tunnel syndrome (CTS) but no evidence of cervical radiculopathy. Cervical myelogram with CT scan followup revealed evidence of multi-level degenerative changes. A 2mm anterolisthesis of C3 on C4 was only seen on CT scan. There was also left uncinat and facet hypertrophy producing moderate left neuroforaminal stenosis. There was osteophyte formation. M.D. noted on 02/11/2008 that the injured individual had been treated for two previous back injuries in xxxx and xxxx and had undergone a PRIDE program. The injured individual has undergone various cervical injections by Dr. without any significant benefit. Dr. has kept her in an off work status and continued to prescribe medications. He has recommended a cervical disc replacement procedure.

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

The injured individual is a female who sustained a work-related injury on xx/xx/xx. She then underwent a two level cervical discectomy and fusion in 03/2006. There is no information regarding how she did following this surgery. She then began seeing Dr. in 2007. Electrodiagnostic testing has only revealed mild left carpal tunnel syndrome. MRI, CT scan and myelogram has shown evidence of degenerative changes at multiple levels in the cervical spine. Her pain generator has not been clearly defined based either on imaging or objective physical findings. Dr. has recommended a cervical disc replacement procedure despite the lack of identification of her pain generator.

The Official Disability Guidelines:

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 six 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 05/28/2007 in a draft proposal that it was rejecting coverage of artificial spinal disc replacement surgery no matter which disc was used. (CMS, 2007) On 07/16/2007 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 one to two 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. (Haldeman, 2008)

The injured individual is a smoker and her morbid obesity put her at significant increased risk of morbidity and mortality. It is not clear how the injured individual responded to the index surgical procedure and whether she had returned to work. She has been off work at least since November of 2007. The Official Disability Guideline considers the procedure experimental at this time since it is lacking long term followup.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES