

Independent Resolutions Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW: September 25, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity of neck spine disk surgery, removal of vertebral body, remove vertebral body ad, microsurgery add-on, inject for spine disk X, neck spine fusion, additional spinal; fusion, observation care, apply spine prosth devic, spinal bone autograft, insert spine fixation DE, treat neck spine fracture, treat each add spine FX, assistant surgeon, non emergency inpatient.

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

Rehab notes, 07/26/06 to 08/7/06, 10/02/07 to 11/27/07, 12/05/07 to 05/05/08, 06/13/08

Cervical MRI, 8/4/06

EMG/NCS, 08/28/006

Office note, Dr. 09/14/06

Office notes, Dr. 02/06/07, 12/04/07, 05/14/08, 08/12/08

Office note, Chiro, 07/05/07, 08/08/07

Rehab note, Dr. 10/16/07

Review, Dr. 08/20/08

Review, Dr 8/27/08

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male with complaints of neck pain and bilateral upper extremity pain. The cervical MRI, dated 08/04/06, showed at C3-4 a right foraminal disc herniation with moderate spondylosis. Impingement upon the right C4 nerve root sleeve was identified with severe narrowing of the right neuroforamen. At C4-5, an annular disc bulge with spondylosis was seen. Severe narrowing of the right neuroforamen was identified. The C5-6 level revealed flattening of the thecal sac with moderate narrowing of the right neuroforamen.

The 08/28/006 electromyography revealed an indication of bilateral C6 and right greater than left C7 acute radiculopathy with greater power reduction in the C6 distribution on the left and greater reductions in the C7 on the right. There was also an indication of significant median nerve compression at both wrists. Dr. of pain management began treating the claimant for cervical and lumbar spine pain on 09/14/06. On 02/06/07, Dr. saw the claimant for neck and bilateral arm pain, worse than left. Examination revealed spasm to the cervical and upper thoracic area. Trigger point was noted. Positive compression was noted. Mild weakness with elbow flexion and wrist extension on the left and paresthesias in the C6-7 nerve root distribution on the left was reported. There was decreased biceps stroke on the left. Spurling was equivocal on the left. X-rays of the cervical spine that day including flexion extension views revealed C3-4 and C5-6 spondylosis with no cervical lordosis. Dr. saw the claimant on 05/14/08. The claimant noted good results from his lumbar surgery. Dr. recommended continued rehabilitation and off work. Dr. saw the claimant on 08/12/08. Dr. noted that the MRI of the cervical spine showed herniated nucleus pulposus and correlated with his clinical examination and that the claimant had instability at C5-6 and C6-7 with abnormal extension angle with motion greater than 11 degrees from extension to forward flexion at both levels. Examination was essentially the same. Dr. felt that the claimant had failed conservative management and recommended surgery. The peer reviews noted the request was for anterior cervical discectomy and fusion at C5-7.

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

The requested surgical intervention, which appears to be an anterior cervical discectomy and fusion, multilevel, with arthrodesis and cages, anterior instrumentation C5-6 and C6-7 is not medically necessary based on review of this medical record and therefore the CPT codes submitted for review are not applicable.

This claimant has had neck and radicular arm symptoms for more than xx years, and it is not clear why the surgery is being requested at this time.

The 08/04/06 cervical MRI documents C5-6 changes as well as C3-4 and C4-5 changes, and it is not clear why a C5-6 and C6-7 operative procedure is being requested.

While this reviewer understands the 08/28/06 EMG documents C6 and C7 changes, it is not clear exactly where those were occurring and not clear that the requested surgical intervention is actually going to deal with those changes. Plus, there is no recent MRI testing documenting the current anatomic condition.

ODG guidelines for surgery document the use of surgery when there are motor and reflex changes, as well as when imaging correlates with the symptoms and positive physical findings. In this case, it is not clear that the imaging studies of two years ago actually totally correlate with the subjective complaints, physical findings, and EMG testing. Therefore, this requested surgical intervention is not medically necessary based on review of this medical record.

Official Disability Guidelines Treatment in Workers' Comp 2008 Updates, neck and upper back

Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See [Discectomy/laminectomy/laminoplasty](#).) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone (for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. ([Bertalanffy, 1988](#)) ([Savolainen, 1998](#)) ([Donaldson, 2002](#)) ([Rosenorn, 1983](#)) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. ([Bambakidis, 2005](#)) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. ([Savolainen, 1998](#)) ([Dowd, 1999](#)) ([Colorado, 2001](#)) ([Fouyas-Cochrane, 2002](#)) ([Goffin, 2003](#)) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. ([Wieser, 2007](#)) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

(1) *Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute:* Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. ([Jacobs-Cochrane, 2004](#)) ([Abd-Alrahman, 1999](#)) ([Dowd, 1999](#)) ([Martins, 1976](#)) ([van den Bent, 1996](#)) ([Savolainen, 1998](#)) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. ([Ragab, 2006](#)) ([Eck, 2002](#)) ([Matsunaga, 1999](#)) ([Katsuura, 2001](#)) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. ([Yamamoto, 1991](#)) ([Abd-Alrahman, 1999](#))

(2) *Fusion with autograft versus allograft:* The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). ([Jacobs-Cochrane, 2004](#)) ([McConnell, 2003](#)) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. ([Younger, 1989](#)) ([Sawin, 1998](#))

([Sasso, 2005](#)) Autograft is thought to increase fusion rates with less graft collapse. ([Deutsch, 2007](#)). See [Decompression, myelopathy](#).

(3) *Fusion with autograft with plate fixation versus allograft with plate fixation, Single level:* A recent retrospective review of patients who received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients. ([Samartzis, 2005](#))

(4) *Fusion with different types of autograft:* The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. ([McGuire, 1994](#))

(5) *Fusion with autograft versus fusion with autograft and additional instrumentation:*
Plate Fixation: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. ([Wright, 2007](#)) See [Plate fixation, cervical spine surgery](#).

Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). ([Poelsson, 2007](#)) ([Varuch, 2002](#)) ([Hacker 2000](#)) See also [Adjacent segment disease/degeneration](#) (fusion).

(6) *Fusion with allograft alone versus with allograft and additional instrumentation:*
Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level procedures and 72% of two-level procedures. ([Kaiser, 2002](#)) ([Martin, 1999](#)) See [Plate fixation, cervical spine surgery](#).

Complications:

Collapse of the grafted bone and loss of cervical lordosis: collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. ([Trojanovich, 2002](#)) ([Herrmann, 2004](#)) ([Katsuura, 1996](#)) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. ([Poelsson, 2004](#)) ([Haden, 2005](#)) ([Poelsson, 2007](#)) ([Hwang, 2007](#))

Pseudoarthrosis: This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. ([Kuhns, 2005](#)) ([Mummaneni, 2004](#)) ([Coric, 1997](#))

Anterior versus posterior fusion: In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much

lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. ([Wang, 2007](#))

Predictors of outcome of ACDF: Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, and normal ratings on biopsychosocial tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health. ([Peolsson, 2006](#)) ([Peolsson, 2003](#)) See [Plate fixation, cervical spine surgery](#). See also [Adjacent segment disease/degeneration \(fusion\)](#) & [Iliac crest donor-site pain treatment](#).

Note: FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. ([FDA MedWatch, 2008](#))

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)**