

Applied Assessments LLC

An Independent Review Organization
1124 N. Fielder Road, #179, Arlington, TX 76012
(512) 772-1863 (phone)
(512) 857-1245 (fax)

Notice of Independent Review Decision

DATE OF REVIEW: September 29, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medical necessity for inpatient one day, C5-C6 ACDF with allograft

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
MRI cervical spine, 07/01/08
MRI right shoulder, 07/01/08
Office note, Dr. , 07/08/08, 08/05/08, 08/28/08
Dr. , 07/23/08
EMG/NCV studies, 07/24/08
Denial of requested surgery, 08/21/08, 08/26/08
Physical therapy evaluation summary, 09/05/08

PATIENT CLINICAL HISTORY [SUMMARY]:

This xx year old female was reportedly injured on xx/xx/xx while picking up a heavy box and felt a pop in her neck. The claimant reported neck and back pain that radiated down her right arm into her ring finger. The records revealed a past medical history significant for post-traumatic stress syndrome, bipolar disorder, Epstein Barr and fibromyalgia as well as a prior history of nine lumbar surgeries including fusion and a current one pack per day smoking habit.

MRI of the cervical spine completed on 07/01/08 revealed a mild disc osteophyte complex most prominent in the right paracentral distribution at the level of C5-6 but showed no evidence for central or neuroforaminal stenosis or neural impingement within the cervical spine. A right shoulder MRI completed on 07/01/08 revealed a partial intrasubstance tear/tendinopathy with peritendinitis of the distal supraspinatus and some acromioclavicular arthropathy with mass effect on the myotendinous junction of supraspinatus. X-rays taken on 07/08/08 revealed relatively normal bony anatomy and alignment and a small amount of decreased disc height at C5-6 and C6-7.

The claimant was to undergo EMG/NCV studies and a pain management referral dated 07/23/08 noted Dr. I recommended proceeding with a diagnostic/therapeutic cervical epidural steroid injection due to radicular pain which had not responded to therapy and medications. The claimant was prescribed Lortab and Skelaxin. The EMG/NCV study completed on 07/24/08 revealed evidence of bilateral C5-6 radiculopathy and evidence of mild median motor neuropathy consistent with bilateral carpal tunnel syndrome.

On 08/05/08 Dr. documented the C5-6 epidural steroid injections dulled much of the claimant's pain but she still had considerable pain radiating down the right arm as before. Exam findings revealed continued right shoulder symptoms as well as of tenderness to palpation at approximately the C5-6 level. The claimant was given a steroid injection into the right shoulder.

The surgeon noted the claimant to have C5-6 herniated nucleus pulposus with documented radiculopathy bilaterally at C5-6 which was confirmed by EMG/NCV study. He noted the symptoms to be consistent with the findings. The claimant was sent for physical therapy and a psychiatric evaluation.

The initial physical therapy evaluation completed on 09/05/08 revealed decreased cervical range of motion to 50 percent in all planes except for extension which was decreased to 25 percent. The claimant was noted to have superficial non anatomical tenderness and pain reported throughout all neck structures and was guarded and subjectively limited. The claimant was felt to show signs of symptom magnification and a course of conservative treatment over a 2-3 week period was recommended. There was no psychological evaluation presented for review at this time. The surgeon recommended a C5-6 anterior cervical discectomy and fusion.

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

Additional discectomy and fusion at C5-6 with allograft is not medically indicated and appropriate in this xx-year-old female with a history of smoking. She has not had a psychiatric evaluation. She has just had physical therapy most recently. She has no evidence of neurocompressive lesion or progressive neurologic deficit or myelopathy. In addition, she has no evidence of instability, tumor or infection. An MRI done 07/01/08 demonstrates degenerative change at the C5-6 level.

Conservative measures need to be further exhausted prior to undergoing such a fusion surgery given that she has no neurologic impairment and these are degenerative findings on imaging. Based upon this surgery is not indicated.

Official Disability Guidelines Treatment in Worker's Comp 2008 Updates: Neck & Upper Back -- Fusion, anterior cervical

Fusion, anterior cervical:

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. ([Peolsson, 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)