

Notice of Independent Review Decision

**DATE OF REVIEW:** February 9, 2011

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Cervical Total Disc Replacement C5-6 versus Anterior Cervical Fusion at C5-6.

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

This reviewer is a Board Certified Orthopedic Surgeon with 43 years of experience.

**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)

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.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

On September 3, 2009, an MRI of the right shoulder was performed. Impression: Small severe grade partial articular surface tear of the anterior distal aspect of

the right supraspinatus tendon. Moderate to severe arthrosis of the acromioclavicular joint as interpreted by, M.D.

On September 15, 2009, the claimant was evaluated by M.D. He presented with complaints of persistent right upper extremity pain, numbness and tingling. The pain radiates out of his neck. An MRI of the cervical spine shows some mild spondylotic disease with minimal protrusions, but no significant disk herniation, or stenosing lesion obvious on films. Impression: Cervical radicular syndrome, unknown etiology. Dr. prescribed Lyrica and physical therapy.

On September 22, 2009, the claimant was evaluated by, M.D. with complaints of left neck and arm pain. The pain is reproduced with holding his arm or head in certain positions and his whole hand will go numb. Lyrica his helping. Cervical spine is nontender, and has some slight hypertonicity in the right. He is able to reproduce arm symptoms. Reflexes are symmetrically diminished. He does have some weakness in the right grip compared to the left and has diminished sensation involving the entire right hand, palmar aspect worse than dorsal. Physical therapy was recommended. Diagnoses: Subacute right neck pain with intermittent radiculitis. Bilateral neural foraminal narrowing at C6-7.

On September 30, 2009, the claimant began physical therapy at the Back Institute 2-3 times a week for 3 weeks.

On October 2, 2009, an EMG of the right upper extremity was performed. Impression: Essentially normal study. There is no significant electrodiagnostic evidence of a disorder involving the lower motor neurons or muscles of the right upper limb and cervical paraspinals as interpreted by M.D.

On October 23, 2009, the claimant was re-evaluated by M.D. He has completed 6 sessions of physical therapy which does seem to be helping his pain by 50%. He has moderate pain in the arm and neck when he moves that he reports is better overall. He continues taking Tylenol, and Skelaxin. He is to continue physical therapy. Diagnosis: Improving cervical radiculitis following work-related injury. Bilateral neuroforminal narrowing at the C6-7.

On November 9, 2009, the claimant was re-evaluated by M.D. He neck pain is 3/10 and arm pain is 2/10. He is taking Tramadol and Skelaxin. He is doing home exercise. He would like to proceed with an ESI.

On December 9, 2009, the claimant was re-evaluated by, M.D. He had an ESI 2 ½ weeks ago which provided 60% relief. He continues to have decreased sensation primarily in the C6 distribution but also some C7 overlap. A second ESI was recommended.

On January 7, 2010, M.D. performed a second ESI at C6-7.

On March 23, 2010, the claimant was evaluated by, M.D He is having depressive symptomatology despite his Lexapro. His Lexapro was increased to 20 mg and was prescribed Darvon. He continues in the CoPE program.

On March 30, 2010, the claimant was re-evaluated by, M.D, He continues in the CoPE program and his doing better. He discontinued all his medications on Friday. He is to continue Lexapro and try Talwin.

On April 6, 2010, the claimant was re-evaluated by M.D. He has been using Tramadol with has been working better. He is making progress in the CoPE program.

On April 22, 2010, the claimant was re-evaluated by, M.D. He is improving. His pain level is not much better but he is functionally making dramatic improvements. He has a partial rotator cuff tear and C6 radiculopathy. He would like to avoid surgery.

On May 25, 2010, the claimant was re-evaluated by, M.D. He is at a medium PDL. He thinks is problem is more of the shoulder than the neck. He has a TENS unit which helps.

On August 4, 2010, the claimant was re-evaluated by M.D. Spurling maneuver is positive for local pain on the base of the neck. Decreased sensation involving the medial aspect of the forearm.

On August 20, 2010, an MRI of the cervical spine was performed. Impression:  
1. Slight retrolisthesis of C3 on C4 with 3 mm broad based ventral defect representing disk and/or spur. The AP diameter of the spinal canal is 8-9 mm. There is deformity of the anterior spinal cord without direct cord intact. Mild left and moderate right neural foraminal narrowing is seen. 2. 2 mm posterior osteophytes at C4-5. The AP diameter of the spinal canal is 9 mm. Moderate bilateral neural foraminal narrowing is seen. 3. 3-4 mm broad based ventral defect at C6-7 with disk minimally exceeding posterior osteophytes. There is impression on the anterior thecal sac greater to the left of the midline deforming the anterior spinal cord without direct cord contact narrowing the central canal to 9 mm. Severe left and moderate severe right neural foraminal narrowing is seen. 4. 2-3 mm broad based posterior disk protrusion at C5-6 lateralizing to the right of midline. Moderate bilateral neural foraminal narrowing is seen as interpreted by, M.D.

On August 30, 2010, the claimant was re-evaluated by M.D. He is having shoulder pain. Dr. needs to know how much of this is neck or shoulder. To that extent, doing at C6-7 injection will help clarify that. If that gets rid of all the neck, shoulder and arm symptoms, then we will know that that is the culprit. If it does not affect the shoulder, then Dr. can proceed with definitive treatment on that. A C6-7 injection for diagnostic and therapeutic purposes.

On October 7, 2010, the claimant was re-evaluated by M.D. He had a transforaminal injection at C6-7 on the right. His pain level when from a 5 or 6 to a 0 and lasted for a few days. He did not have to take any medication during that time. However the pain did return. He does have some improvement in the neck and arm pain. The numbness is the same. He would probably benefit from surgery.

On October 13, 2010, the claimant was evaluated by, M.D., an orthopedic surgeon. Dr. stated he is a surgical candidate at the C6-7 level. First a Cervical Myelogram/CT scan should be performed to determine how much of the foramen is decompressed.

On October 28, 2010, a CT Myelogram of the cervical spine was performed. Impression: 1. Slight decreased filling of the right C6 nerve root sleeve on the myelogram. 2. Minimal posterior spondylosis noted from C3-4 through C6-7.

On November 2, 2010, the claimant was re-evaluated by, M.D. He is still having a problem with his right shoulder as well as some pain under the arm and numbness of the right thumb. Deep tendon reflexes are symmetrically absent. There is diffuse paraspinal tenderness and trapezii tenderness. He is a good candidate for anterior cervical fusion. Assessment: Neck, right shoulder, and right arm, paresthesias to the thumb with negative EMG with previously good response to C6-7 injection with a week's worth of pain with moderate foraminal stenosis on the right C5-6 level with decreased filling of the nerve root on the myelogram with clinical signs of more of a C6 radiculopathy. Co-existent rotator cuff injury both since on the job injury on xx/xx/xx.

On December 2, 2010, the claimant was evaluated by Ph.D. for a psychological evaluation. He is clear to proceed with surgery, from a psychosocial perspective, with good prognosis for pain reduction and functional improvement.

On December 9, 2010, M.D., an orthopedic surgeon, performed a utilization review on the claimant Rational for Denial: While the claimant does have a positive Spurling's, which meets ODG indications, the next criteria should be evidence of motor deficit, reflex changes or positive EMG findings that would correlate with the cervical level. At this time, the reflexes are noted to be absent symmetrically and bilaterally. The EMG was noted to be negative and there is no motor deficit noted. Therefore, it is not certified.

On January 4, 2011, M.D., orthopedic surgeon, performed a utilization review on the claimant. Rational for Denial: The submitted records show a history a cervical pain with reported radiation into the right upper extremity that is not support by EMG evidence. There is no clear objective evidence of radiculopathy which would be exclusions for the performance of cervical artificial disc replacement. His physical examination is not consistent with a C5-6 lesion. He has undergone a CPMP which is for patients who are not surgical candidates and are designed to return patients to work. Therefore, it is not certified.

### **PATIENT CLINICAL HISTORY:**

On xx/xx/xx, the claimant was helping to essentially dig something out of the ground which involved shoveling, chopping and lifting for about 4 hours and injured his cervical spine and right shoulder.

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

The previous decisions are upheld based on the following: Per the EMG performed on October 2, 2009 by M.D., there was no evidence of radiculopathy. The claimant's reflexes are documented on clinical examinations to be absent symmetrically and bilaterally, which is in all medical probability physiologically normal for him. Lastly, there is a lack of documentation of any neurological motor changes.

### **Per ODG:**

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, gainful employment, higher preoperative NDI 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, litigation and workers' compensation. ([Anderson, 2009](#)) ([Poelsson, 2006](#)) ([Poelsson, 2003](#)) Patients who smoke have compromised fusion outcomes. ([Poelsson, 2008](#))

See [Plate fixation, cervical spine surgery](#). See also [Adjacent segment disease/degeneration](#) (fusion) & [Iliac crest donor-site pain treatment](#).

*Use of Bone-morphogenetic protein (BMP):* 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](#)) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). ([Cahill-JAMA, 2009](#))

For hospital LOS after admission criteria are met, see [Hospital length of stay](#) (LOS).

**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)**