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Notice of Independent Review Decision

**DATE OF REVIEW:** 1/27/12

**IRO CASE NO.:**

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

Item in dispute: 2-3 Day Inpatient Stay with Anterior Cervical Decompression with Fusion of C4-5 and C5-6

**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 determination should be:

Upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

1. 05/05/11 – Clinical Note – MD
2. 05/10/11 – MRI Cervical Spine
3. 05/10/11 – MRI Lumbar Spine
4. 08/10/11 – Clinical Note – MD
5. 08/24/11 – Clinical Note – MD
6. 09/30/11 – Electrodiagnostic Studies
7. 10/19/11 – Clinical Note – MD
8. 10/27/11 – Operative Report
9. 11/07/11 – Clinical Note – MD
10. 11/09/11 – Behavioral Evaluation – MS, LPC
11. 11/23/11 – Utilization Review Determination
12. 12/05/11 – Clinical Note – MD
13. 12/06/11 – Appeal of Adverse Determination

**PATIENT CLINICAL HISTORY (SUMMARY):**

The patient is a male who was involved in a motor vehicle accident on xx/xx/xx, resulting in moderate damage to the claimant's vehicle. The patient saw Dr. on 05/05/11 with complaints of neck and back pain, as well as spastic pain in the right foot. Physical exam revealed slight

restriction in range of motion of the cervical, thoracic, and lumbar spine. Range of motion testing caused pain and spasm throughout the spine. Straight leg raise was to 70 degrees on the left and 60 degrees on the right. The patient was assessed with hyperextension-hyperflexion injury of the cervical spine, brachia neuritis, lumbar radiculitis,
hyperflexion-hyperextension injury of the thoracic spine, and edema of the ankle/foot joints. The claimant was recommended for 12 to 18 sessions of physical therapy. MRI of the cervical spine performed 05/10/11 revealed straightening of the cervical lordosis. There was generalized decrease in signal intensity, suggestive of desiccation. There were posterior annular tears at C4-5 and C5-6. At C4-5, there was a broad-based central-right paracentral disc herniation, causing mild narrowing of central and right lateral spinal canal. At C5-6, there was a broad-based central-right paracentral disc herniation, causing mild narrowing of the central and right lateral spinal canal.

MRI of the lumbar spine performed 05/10/11 revealed a mild diffuse disc herniation at L4-5, causing mild indentation on the thecal sac. At L5-S1, there was a mild diffuse disc herniation causing mild indentation of the thecal sac. There was partial loss of lumbar lordosis. The vertebrae were normal in height, alignment, and signal intensity. The intervertebral discs showed normal hydration and maintained disc heights.

The patient saw Dr. on 08/10/11 with complaints of pain to the neck and back. The patient reported no relief from physical therapy. Physical exam revealed cervical paravertebral tenderness with pain radiating down the left shoulder. Motor function was intact throughout the upper extremities. Sensation was decreased in the left C6 dermatome. The reflexes were brisk and equal bilaterally. There was lumbar paravertebral tenderness and mild spasm radiating to the buttocks bilaterally. Straight leg raise was reported to be positive on the left at 60 degrees. Sensation was decreased in the left L5 dermatome. Radiographs of the cervical spine revealed no obvious fracture, avulsion injury, or degenerative changes. Radiographs of the lumbar spine revealed no obvious fracture, avulsion injury, or degenerative changes. The patient was prescribed Lyrica and Naprelan.

Electrodiagnostic studies performed 09/30/11 revealed evidence of left median motor neuropathy, right ulnar motor neuropathy, left C5 and/or C6 radiculopathy, and left tibial motor neuropathy.

The patient saw Dr. on 10/19/11 with continued pain complaints. Physical exam revealed cervical paravertebral tenderness with pain radiating down the left shoulder. Motor function was intact throughout the upper extremities. Sensation was decreased in the left C6 dermatome. The reflexes were brisk and equal bilaterally. There was lumbar paravertebral tenderness and mild spasm radiating to the buttocks bilaterally. Straight leg raise was reported to be positive on the left at 60 degrees. Sensation was decreased in the left L5 dermatome. The patient was assessed with cervical herniations with radiculopathy and lumbar herniations. The patient was recommended for left C5 and C6 transforaminal epidural steroid injections.

Dr. performed left C5 and C6 transforaminal epidural steroid injections on 10/27/11.

The patient saw Dr. on 11/07/11 with complaints of neck pain with progressive weakness to the left arm and numbness of the left hand. Physical exam revealed cervical paravertebral tenderness with trapezial tenderness. Spurling's was positive to the left. There was weakness of C6 on the left. Sensation was decreased in the left C5 and C6 dermatomes. The reflexes were brisk and equal bilaterally. The patient was recommended for C4-5 and C5-6 cervical discectomy and fusion.

The patient was cleared for surgical intervention from a psychological standpoint on 11/09/11.

The patient was also recommended for 6 sessions of individual psychotherapy.

The request for 2-3 day inpatient stay with anterior cervical decompression with fusion of C4-5 and C5-6 was denied by utilization review on 11/23/11.

The patient demonstrated clear evidence of radiculopathy, with radicular arm pain to the left, positive Spurling's sign, and positive electrodiagnostic studies. However, the MRI study revealed pathology to the right and not to the left. As the imaging studies do not correlate with the patient's subjective complaints and physical exam findings, the surgical request was denied.

The patient saw Dr. on 12/05/11 with complaints of neck pain with progressive weakness to the left arm and numbness of the left hand. Physical exam revealed cervical paravertebral tenderness with trapezial tenderness. Spurling's was positive to the left. There was weakness of C6 on the left. Sensation was decreased in the left C5 and C6 dermatomes. The reflexes were brisk and equal bilaterally. The patient was recommended for C4-5 and C5-6 cervical discectomy and fusion.

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

The clinical documentation provided for review does not support the request for 2-3 Day Inpatient Stay with anterior Cervical Decompression with Fusion of C4-5 and C5-6. The claimant has weakness and sensory loss in the left C5 and C6 dermatomes that is inconsistent with the cervical MRI findings. There are no clear neurocompressive lesions noted to the left at C4-5 and C5-6 that would reasonably account for the claimant's objective findings. There is canal narrowing to the right only on the MRI studies. Additionally, the patient has not exhausted a reasonable course of conservative treatment. The patient has undergone one epidural steroid injection only. The clinical notes do not indicate that the patient has attempted any physical therapy or medication management that would address the reported symptoms. Since the requested anterior cervical discectomy and fusion at C4-5 and C5-6 is not supported as medically necessary, the 2-3 inpatient stay would not be required. As the clinical documentation provided for review does not meet current evidence based guideline recommendations for the requested procedures.

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

**REFERENCES:**

Official Disability Guidelines, Online Version, Neck & Upper Back Chapter.

**Cervical Fusion:** 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. (Troyanovich, 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, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical 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) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 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)