CASEREVIEW

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Notice of Independent Review Decision

DATE OF REVIEW: November 11, 2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Inpatient Anterior Cervical Discectomy and Fusion at C5-6 and C6-7; Structural bone allograft; Anterior spinal instrumentation.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
This physician is Board Certified by American Board of Orthopedic Surgeons with over 40 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:
07/22/11: Medical report by MD at Orthopaedic Center, P.A.

07/26/11: Operative report by MD
07/29/11: Medical report by MD at Orthopaedic Center, P.A.
08/03/11: Operative report by MD
08/11/11: Medical report by MD at Orthopaedic Center, P.A.
08/24/11: Medical report by MD at Orthopaedic Center, P.A.
09/20/11: EMG/NCV of the right upper extremity by MD at Orthopaedic Center, P.A.
09/26/11: Medical report by MD at Orthopaedic Center, P.A.
10/05/11: UR performed by MD
10/10/11: Medical report byMD at Orthopaedic Center, P.A.
10/21/11: UR performed by MD

PATIENT CLINICAL HISTORY [SUMMARY]:
The claimant was injured in a xxxxxx and is status post right shoulder rotator cuff repair, status post right shoulder arthroscopic debridement and lysis of adhesions, subacromial decompression and rotator cuff repair 10/13/10, status post right carpal tunnel release and cubital tunnel release and thumb carpometacarpal joint arthroplasty 03/30/08.

On July 22, 2011, the claimant was re-evaluated by MD for complaints of worsened pain in his neck with radiation into his right shoulder and both arms. He had numbness and tingling in both arms and hands with weakness in both arms. On physical examination deep tendon reflexes were hypoactive, sensory examination was normal in the upper and lower extremities, and range of motion of the cervical spine was limited in flexion, extension, rotation and lateral tilting. ROM did reproduce a radiculopathic symptom. There was evidence of tenderness and spasm to palpation.

On July 26, 2011, Operative report by MD. Postoperative diagnosis: Cervical radiculopathy. Procedure: Cervical epidural steroid injection, C5-6 and C6-7.

On July 29, 2011, the claimant was re-evaluated by MD who reported he had complaints of throbbing and headaches since undergoing the CESI on 07/26/11. Dr. recommended attempting conservative therapy for a few more days, if no improvement then would proceed with a blood patch.

On August 3, 2011, Operative report by MD. Postoperative diagnosis: Low-pressure headache. Procedure: Blood patch, T1-2.

On August 11, 2011, the claimant was re-evaluated by MD who noted the Blood patch helped but he still had intermittent headaches with activity. On physical examination there was some weakness of the biceps in the right and the triceps, otherwise all muscle groups tested in the upper and lower extremities were a grade 5, on a scale of 1-5. Deep tendon reflexes were hypoactive. There were no long-tract signs. Sensory examination was normal in the upper and lower extremities. There was some limitation in range of motion of the right shoulder. Range of motion of the cervical spine was limited in flexion, extension, rotation and lateral tilting. It reproduced a radiculopathic symptom. There was tenderness and spasm to palpation.

On August 24, 2011, the claimant was evaluated by MD for persistent neck and arm pain and headaches since an injury of xx/xx/xx. The pain was reported to radiate from the neck into the right paracervical muscles, along the right rhomboid, and into the right lateral arm and forearm, going down into the right fourth and fifth digits. According to Dr. a cervical myelogram and a post-myelographic CT in March of 2011 showed minimal spondylosis at C2-3, mild spondylosis at C3-4, facet arthrosis at C4-5, and herniated nucleus pulposus and spondylosis at C5-6 with narrowing of the neural foramina, more on the right than on the left. C6-7 showed no herniated nucleus pulposus. An MRI of the cervical spine was completed in June of 2010 that showed moderate changes at multiple disc levels and disc degeneration. There was also disc degeneration at C6-7, although the cervical myelogram and post Myelographic CT scan did not reveal any herniation of the disc. There were degenerative changes also at C3-4, C4-5, and C5-6. There was a left-sided protrusion at C4-5. There was a right-sided protrusion at C5-6. There was a small right-sided protrusion at C6-7, but this was not noted on the myelogram or post-myelographic CT scan done this year. Dr. also reported the claimant had not undergone any electrodiagnostic testing. On physical exanimation he was tender over the right cervical paraspinal area. Spurling test was mildly positive on the right. He was tender in the rhomboid muscles. He had some limitation of abduction and external rotation of the right shoulder, but he had a previous rotator cuff repair. He had a mildly positive Tinel's sign at the right cubital tunnel. He had a negative Tinel's sign at the carpal tunnel. He did have a Dupuytren's contracture in the palm. There was some decreased sensation along the fourth and fifth digits. He had good power of biceps, triceps, wrist extensors and flexors. He had good grip strength bilaterally. Impression: Post rotator cuff tear of the right shoulder, doing reasonably well, and cervical radiculopathy with cervical herniated nucleus pulposus. Dr. recommended an EMG/NCV of the right upper extremity.

On September 20, 2011, EMG/NCV of the right upper extremity performed by MD revealed: 1. Abnormal study. 2. Electrodiagnostic evidence of an acute or chronic, right C6-7 radiculopathy, with evidence of ongoing denervation. 3. There was also evidence of a right sensory, superficial radial neuropathy, consistent with axonal loss and demyelinating patter. 4. There was also evidence of a right sensory, ulnar mononeuropathy, consistent with axonal loss and demyelinating pattern, unable to localize. On physical examination Dr. found motor testing to be 5/5 in the bilateral upper extremities, reflexes were 2+/4 and symmetric at triceps, biceps, BCRL, and sensory testing was intact expect decreased ulnar sensation on the right.

On September 26, 2011, the claimant was re-evaluated by MD for continued severe neck pain with decreased grip strength and decreased use of the right arm. On physical examination Dr. found decreased range of motion, positive Spurling's test on the right, decreased grip strength, decreased finger extensors, and decreased sensation both along the C-6 and C-7 dermatome. Dr. stated that the claimant had undergone physical therapy, medications, a home exercise program and a CESI with only temporary improvement of his symptomatology and therefore recommended an anterior cervical discectomy and fusion at C5-6 and C6-7.

On October 5, 2011, MD performed a UR. Rationale for Denial: The recent CT scan does not confirm disc herniation or stenosis at C6-7. Thus, without the benefit of peer discussion based on the above issues, I cannot approve the proposed surgery at C6-7 as medically indicated and necessary at this time and thus denied the entire surgery.

On October 10, 2011, the claimant was re-evaluated by MD who found on physical examination that his Spurling's test was negative. Lhermitte's sign was negative. He had some weakness of grip on the right, but stated he had a previous cubital tunnel and carpal tunnel release on the right. Impression: 1. Persistent cervical radiculopathy. 2. EMG evidence of cervical radiculopathy C6-7. 3. Multilevel disc degeneration and spondylosis. 4. MRI evidence of an HNP at C6-7 on the right. 5. Non-insulin dependent diabetes. 6. On Plavix. 7. Chronic pain. Dr. was going to appeal the denial of the surgery.

On October 21, 2011, MD performed a UR. Rationale for Denial: The claimant does not have objectified radiculopathy on physical examination. Independent examination documented intact reflexes and strength in the upper extremities despite evidence of acute right C6-7 radiculopathy on chronic radiculopathy. CT myelogram did not objectify any disc herniation. There was disc space narrowing with posterior disc osteophyte complex, C5-6 there was mild posterior disc osteophyte complex without significant canal stenosis and osteophytosis resulted in mild encroachment on the right neural foramen. There were no flexion/extension views objectifying cervical instability. Guidelines indicate cervical fusion for degenerative disease resulting in axial neck pain with no radiculopathy remains controversial and lower levels of care remain the choice if there is no evidence of instability.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION:
The previous decisions have been upheld. Physical examinations on numerous occasions revealed a completely intact neurological exam except for numbness which could be explained by his history of carpal tunnel and ulnar neuropathy. In addition, imaging tests are inconclusive in that they are not consistent in identifying a specific area of herniated disk. The ODG Guidelines indicate cervical fusion for degenerative disease resulting in axial neck pain with no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. There were no flexion/extension films identifying instability. Therefore, based on ODG, the proposed cervical fusion at C6-7 is not medically supported.

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. (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)
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)**