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Notice of Independent Review Decision

DATE OF REVIEW:
01/28/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Examination under anesthesia, anterior cervical decompression, discectomy, arthrodesis with cages and plate at C5-6 with two day inpatient length of stay (LOS).

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 determinations should be: **Upheld**

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.
Request for examination under anesthesia, anterior cervical decompression, discectomy, arthrodesis with cages and plate at C5-6 with two day inpatient length of stay is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:
The injured individual is a female who was reported to have sustained a work-related injury on xx/xx/xx. The Employer's First Report of Injury dated xx/xx/xx described the mechanism of injury as lifting a box and was unsure of the weight. The injured individual noted that she was on a ladder lifting. The box hit the shelf and bounced back hitting her left side of her face. It almost knocked her off ladder, but she did not fall. She was evaluated by Medical Group on xx/xx/xx. His examination and diagnosis was consistent with a right rhomboid strain and myalgias. There was no specific mention of a cervical injury on his visit or the note on 05/30/2006. M.D. noted on 06/13/2006 the diagnoses of

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cervical and lumbar strain. Emergency room visits on 08/23/2006 and 09/11/2006 to Hospital documented normal neurological examinations on both dates. Plain x-rays revealed degenerative changes at C5-C6 with spur formation. A cervical MRI on 08/02/2006 reported posterior and central herniation of C3-C4 of 2mm and posterior and central herniation of C5-C6 of 2mm. There was no evidence of neural compromise at either level. The injured individual had been treated by multiple chiropractic and pain management physicians. M.D. (Orthopaedic) performed an Independent Medical Exam (IME) on 01/25/2007 and felt that the injured individual's diagnosis was at most a "sore neck". She underwent multiple Functional Capacity Exams (FCEs) that revealed submaximal effort. D.C. placed the injured individual at maximum medical improvement (MMI) with 5% whole person (WP) impairment rating on 08/04/2007 which was later disputed. The injured individual continued to be seen by D.C. Her symptoms continued despite treatment. Statutory MMI was on 07/15/2008 with a 5% WP impairment rating. She apparently changed treating providers to D.C. on 10/24/2008. Behavioral health assessment was performed on 11/10/2008. She documented a severe level of anxiety and a severe to extreme level of depression. An MRI of the lumbar spine was done on 12/02/2008. The lumbar spine MRI revealed no significant pathology. M.D. first evaluated her on 06/24/2008 following the injury. Dr. reported that she complained of neck and bilateral arm pain left greater than right. His diagnosis was cervical herniation of nucleus pulposus (HNP) at C5-C6 with stenosis and radiculopathy. He advised the injured individual that she could either live with her symptoms or undergo the requested procedure. M.D. placed the injured individual at statutory MMI as of 07/16/2008 on a Designated Doctor Exam (DDE) performed 01/12/2009 with a 5% whole person impairment rating.

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

The injured individual is a female who was alleged to have sustained a work- related injury on xx/xx/xx. The documented mechanism of injury and initial physical findings documented in the medical record were at most consistent with a cervical strain. Plain films revealed degenerative changes at C5-C6 with spur formation, which is pre-existing or a "disease of life". The evidence-based Official Disability Guidelines (ODG) would have expected resolution of the effects of the work injury within six to eight weeks with conservative management. The injured individual has undergone extensive evaluation and treatment without any clinical improvement or change in functional status. The injured individual worked approximately nine months prior to injury. She has not returned to work. MRI of the cervical spine showed no evidence of neurological compromise, but degenerative changes. Electrodiagnostic studies were negative for radiculopathy. She is now over two and one half years post injury and has self-reported pain levels of 10/10. Psychological assessment has revealed severe to extreme levels of anxiety and depression. Dr. has requested a one level cervical discectomy with fusion with the use of cages and plate. The pain generator has not been clearly defined or documented.

ODG Indications for Surgery -- Discectomy/laminectomy (excluding fractures):
Washington State has published guidelines for cervical surgery for the entrapment of a single nerve root and/or multiple nerve roots. (Washington, 2004) Their recommendations require the presence of all of the following criteria prior to surgery for each nerve root that has been planned for intervention (but ODG does not agree with the electromyogram [EMG] requirement):

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A. There must be evidence of radicular pain and sensory symptoms in a cervical distribution that correlate with the involved cervical level or presence of a positive Spurling test.
B. There should be evidence of motor deficit or reflex changes or positive EMG findings that correlate with the cervical level. Note: Despite what the Washington State guidelines say, ODG recommends that EMG is optional if there is other evidence of motor deficit or reflex changes. EMG is useful in cases where clinical findings are unclear, there is a discrepancy in imaging, or to identify other etiologies of symptoms such as metabolic (diabetes/thyroid) or peripheral pathology (such as carpal tunnel). For more information, see EMG.
C. An abnormal imaging (CT/myelogram and/or MRI) study must show positive findings that correlate with nerve root involvement that is found with the previous objective physical and/or diagnostic findings. If there is no evidence of sensory, motor, reflex or EMG changes, confirmatory selective nerve root blocks may be substituted if these blocks correlate with the imaging study. The block should produce pain in the abnormal nerve root and provide at least 75% pain relief for the duration of the local anesthetic.
D. Etiologies of pain such as metabolic sources (diabetes/thyroid disease) non-structural radiculopathies (inflammatory, malignant or motor neuron disease), and/or peripheral sources (carpal tunnel syndrome) should be addressed prior to cervical surgical procedures.
E. There must be evidence that the patient has received and failed at least a 6-8 week trial of conservative care.

The injured individual does not meet the criteria as outlined above. Multiple examiners have not objectively documented any evidence of nerve root compromise or findings consistent with radiculopathy. She has had a negative EMG and the MRI did not reveal any evidence of nerve root compromise.

Pre-operative evaluation:
MRI: This is a very sensitive test for radicular disorders but has a lower negative predictive value. Disc bulges have been found in one study in 52% of subjects and protrusions in 27% without back pain. At age 60 years, 93% of subjects in one study had disc degeneration/bulges on MRI. (Boden, 1990)
EMG: Optional for cervical surgery.

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

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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:

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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, 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) 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.
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)

The injured individual has significant psychosocial issues that have not been addressed. She has changed treating physicians several times for unclear reasons. Her treatment appeared to be excessively passive and pain focused. Her pain generator(s) have not been clearly defined despite extensive evaluation and numerous providers. The requested procedure does not meet the ODG criteria for a discectomy or a discectomy combined with fusion.

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Both the Official Disability Guidelines and Medical Disability Advisor recommend investigation and addressing of nonphysical factors (psychosocial, workplace, socioeconomic) in cases of delayed recovery or return to work (RTW).

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:
ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION): Medical Disability Advisor