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DATE OF REVIEW: March 17, 2008

IRO CASE #:

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

This case was reviewed by an orthopedist (Board Certified), Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Anterior cervical discectomy and fusion

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overtuned (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o April 9, 2007 cervical MRI
- o April 16, 2007 cervical x-rays per Dr.
- o September 10, 2007 neuro-consultation of Dr. per referral Dr.
- o October 8, 2007 EMG/NCV report Dr.
- o September 10, 2007 status report Dr. with order for surgery
- o Nurse case management notes covering December 14, 2007 through January 18, 2008, unspecified author
- o December 17, 2007 initial denial for ACDF
- o December 20, 2007 request for reconsideration of the denial for ACDF by Dr.
- o January 15, 2008 denial of final reconsideration for ACDF – additional info requested
- o March 5, 2007 request for IRO

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records, the patient is an employee who sustained an industrial injury to the cervical spine after 20 years of computer work for up to 12 hours per day. The patient is described as 5' 9" in height and 240 pounds. He is followed orthopedically by Dr. per referral of his primary provider, Dr. with a diagnosis of herniated nucleus pulposus at C5-7.

Per a report of Dr. of September 10, 2007 a consultation is provided for opinions regarding cervical spondylosis. The patient reports pain radiating into the right greater than left shoulder, arm and fingers for five years. He reports weakness with numbness and tingling. He complains of dropping objects. His pain level is described as 7-8/10. He takes ibuprofen without significant relief. The patient reports shortness of breath occasionally due anxiety. He has gained 30 pounds in the last 6 months due inactivity. On examination, there is restricted cervical flexion. Left wrist motor strength is 4/5. Sensation is decreased in the entire right hand. Upper extremity reflexes are 2+ and symmetrical. There is a positive Tinel's at the left wrist. Plain films of April 2007 show bone spurs at multiple levels. MRI of April 2007 shows disc protrusions at C5 and left C6-7 with a mild bulge at C3-4. At the C6-7 level the bulge is a 4-5 mm posterior left lateralizing protrusion with spondylosis mildly encroaching upon the left ventrolateral cord with mild to moderate narrowing of the subarachnoid space. New medications will be initiated, as well as

physical therapy and massage.

Electrodiagnostic studies were performed on October 8, 2007 and show findings consistent with left C6 and C7 nerve root irritation and right C6 nerve root irritation.

Per a progress report of December 10, 2007, pain continues and radiates into both arms and is associated with numbness in all fingers. Weakness in both hands continues and the patient complains of difficulty sleeping as well as dizziness and nausea due to pain. He rates the pain as 9-10/10. Physical therapy has not provided relief and he is progressively worsening. On examination, there is new weakness of the left infraspinatus and biceps muscles.

Request for anterior decompression and fusion intervention was not certified on December 17, 2007, with rationale that current evidence per the literature is conflicting about the benefit of fusion in general. Simple discectomy often results in spontaneous fusion. Conservative therapy remains the best choice if there is no instability. More specifically, there is no detailed history of treatment to date. The patient reportedly failed conservative treatment, however, no detailed history of treatment was submitted. Additional information is needed.

On January 15, 2008 final reconsideration for the requested procedures was denied in review with rationale that no detailed history of treatment is submitted. Additional information is needed.

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

The patient has persistent cervical pain, functional limitations and progressive weakness in the upper extremities. Imaging of MRI shows disc protrusions and mild encroachment upon the left ventrolateral cord with mild to moderate narrowing of the subarachnoid space without frank spinal cord or nerve root encroachment. Objective clinical examination findings, however, document weakness in the upper extremities which is corroborated by electrodiagnostic study findings of left C6 and C7 nerve root irritation and right C6 nerve root irritation. The patient is 20 months post injury and has reported persistent pain for the past 5 years and seeks relief with surgical intervention. The Official Disability Guidelines states that cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. In comparison with discectomy only, there is moderate evidence that pain relief after five to six weeks is higher for patients who have discectomy with fusion. Regarding anterior versus posterior approach, regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. 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). The patient has progressive weakness now including the left infraspinatus and biceps muscles. He is a non-smoker and is relatively young. The medical records substantiate progressive neurologic deficits that have not resolved despite medication and therapy. Therefore, my determination is to overturn the previous non-certification of anterior cervical decompression and fusion.

The IRO's decision is consistent with the following guidelines:

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

X 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

The Official Disability Guidelines (2008) – Anterior Discectomy with Fusion:

Fusion is 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.