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Notice of Independent Review Decision

DATE OF REVIEW: June 30, 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 Orthopaedic Surgeon, 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 C5-6

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: Overturned (Disagree)

PATIENT CLINICAL HISTORY
[SUMMARY]:

According to the medical records provided for my review, the patient is a xx-year-old employee who sustained an industrial injury to the cervical and lumbar spine and right first toe on xx/xx/xx associated with a motor vehicle accident.

Cervical MRI of February 14, 2007 shows a central posterior disc herniation measuring 2.5 mm indenting the thecal sac, touching the spinal cord.

Electrodiagnostic studies were performed March 13, 2007 and show some mild carpal tunnel at the right wrist and no evidence of generalized peripheral neuropathy or cervical radiculopathy.

On July 6, 2007 an epidural injection was administered at C5-6. At follow-up on September 19, 2007 the patient reported the injection initially provided relief but the symptoms have returned to the pre-injection level. The patient reports her neck pain radiates up to her head causing headaches. The patient also reports pain going into her right arm and into the right C6 distribution. On examination, there is a positive right Spurling sign and restricted motion, especially extension. With motor testing, there is weakness in grip, wrist extension and elbow flexion on the right. Right brachioradialis reflex is weaker than the left. Recommendation is for discectomy and fusion at C5-6.

The patient was reevaluated on October 5, 2008. The patient continues with neck and low back pain. The examination remains unchanged from last visit, although motor and sensory function are reported as intact. Recommendation for cervical surgery continues. The lumbar MRI was interpreted as normal. Lumbar facet blocks are recommended as well as post-injection therapy.

Request for ACDF was not certified in review on October 8, 2007 with rationale that the literature notes conflicting evidence about the benefit of fusion procedures although they are supported for approved indications. Many patients have found excellent outcomes with simple discectomy alone and have also been found to go on and develop spontaneous fusion after an anterior discectomy. The Cochrane review felt there was conflicting evidence of the relative effectiveness of EITHER procedure. The

request was denied based on the literature and would be reconsidered if additional information was provided.

A request for reconsideration was not certified in review on October 23, 2008 with rationale that, per reports of September 19, 2007 and October 5, 2007 the patient demonstrated inconsistent examination findings in both motor and sensory functions of the right upper extremity. It was also noted that, per the literature sent with the appeal, the results of a discectomy and fusion are essentially identical to simple discectomy and that the MRI, while showing a disc herniation at C5-6 level, does not mention any involvement of the nerve root. It was opined that the patient would not likely benefit from the proposed surgery.

A request was made for an IRO.

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

The literature does not provide firm guidance in regard to cervical fusion procedures and outcomes, and in actual practice, the majority of surgeons consider fusion with discectomy the normal standard for anterior surgery on the neck for HNP. The fusion does allow for less neck pain in the first 3 months, use of a soft rather than a hard collar, and less kyphosis at the site of surgery than discectomy alone. ODG states that cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. The patient had all the correct indications for surgery (ACDF) at the initial request on September 19, 2007. Although it would be nice to have a more current physician evaluation, the delay is procedural due to the denial and not due to the patient or physician. I would not uphold the denial and would agree that surgery is appropriate if the symptoms persist and the exam remains abnormal. Therefore, my determination is to disagree with the previous non-certification and to certify the request for anterior cervical discectomy and fusion C5-6.

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 - Anterior Cervical Discectomy and Fusion 5-7-08:

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, 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.