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DATE OF REVIEW: 12-19-08

IRO CASE #:

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

This case was reviewed by a Orthopaedic Surgery, 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 at C5-6 with 23-hour observation

REVIEW OUTCOME

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

should be: Upheld (Agree)

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a xx-year-old employee who sustained an industrial injury to the neck, right upper extremity, mid back, low back and right lower extremity on xx/xx/xx when the employee bus she was riding in was struck by a train. A passenger from the opposite side of the bus was thrown onto her, knocking her right side into the wall of the bus. Thoracic radiographs of February 5, 2007 were significant for probable T12 fracture.

Lumbar MRI of February 9, 2007 shows a 1-2 mm central disk herniation at L5-S1 impinging upon the subarachnoid space. Right shoulder MRI shows some fluid in the glenohumeral joint, otherwise normal. Cervical MRI shows a 1-2 mm central disk herniation at C5-6 impinging upon the subarachnoid space, otherwise normal.

The medical report of March 1, 2007 indicates the patient is being treated for low back pain that radiates to the right leg, neck pain and right shoulder pain. The patient was recommended to initiate physical therapy and to return in 4 weeks. On April 12, 2008 the patient continued with neck pain and upper extremity symptoms and additional physical therapy and cervical epidural injection was recommended. Epidural injections were not certified on April 23, 2007 with rationale that the MRI does not show nerve root compression. A request for reconsideration was also denied due lack of documentation of neurologic deficits.

Physical therapy notes of July 26, 2007 indicate the patient is not progressing with therapy. She reports cervical traction has increased her symptoms. "She has been very difficult to work with in her treatment sessions. This patient does not exhibit someone with severe pain." The patient reportedly discontinued physical therapy as she did not want to be reevaluated. The patient did return the following day and reassessment was planned for July 28, 2007.

The medical report of June 14, 2007 indicates the patient is performing HEP as additional formal physical therapy has been denied. She reports paresthesias along both forearms. Recommendation is for cervical epidural injections. Cervical epidural injections were not authorized.

The patient was evaluated by a Designate Doctor on July 17, 2008. The patient is using Temazepam and Tramadol for pain. Cervical examination was positive for pain with foraminal compression and restricted range of motion. The cervical, thoracic, lumbar and upper and lower extremity examinations are otherwise essentially normal. The patient is not MMI. Recommendation was for lumbar epidural injection prior to MMI.

The patient returned to physical therapy on July 13, 2007 for neck and upper extremity conditions. On July 30, 2007 the therapist notes no significant change in the patient's condition with 8 sessions of physical therapy. Her questionnaire score responds to severe disability.

The provider administered cervical and lumbar epidural steroid injections on December 18, 2007. On February 2, 2008 the results were reported as "mixed" with good relief of lumbar symptoms but minimal relief of cervical pain. The patient reports going to emergency on January 15, 2008 when her neck got locked up. The patient may require discectomy. Request was made for cervical discogram.

On February 21, 2008 the patient returned to the Designated Doctor. The patient has just reinitiated physical therapy. She reports neck pain and right arm weakness. Prior to MMI the patient is recommended to complete physical therapy, get a myelogram, undergo a final cervical injection and then consider surgery if no improvement. Residual Functional Capacity testing of February 21, 2008 determined the patient is unable to return to her occupation as a Boilermaker which is a heavy strength category occupation.

Cervical epidural steroid injection was administered on April 18, 2008. Discogram followed by CT scan the same date was interpreted as showing a moderate annular tear at C5-6 causing a small herniation with no significant impingement. The discogram was interpreted to show a normal control level at C4-5 and positive concordant pain at C5-6.

The patient's medical records through March 12, 2008 were reviewed for comment by an orthopedic surgeon on April 22 2008. It was opined that the patient's strain injuries and contusions should have resolved over a 4-6 month period. The records indicate negative examination findings regarding neuromuscular deficit and essentially negative x-ray and MRI studies of the spine and shoulder. The non-specific extremity complaints do not correlate with abnormal x-ray or MRI findings or objective physical examination findings. The medical records fail to substantiate a medical necessity for epidural injections or additional evaluations and treatment.

The patient was reevaluated on June 12, 2008 including psychosocial testing which were interpreted to show no psychosocial barriers to recovery. The patient's BHI testing results were interpreted to show no psychological or social reason why she should not improve with treatment. The patient has undergone discogram which was interpreted to show a normal control level at C4-5 and positive concordant pain at C5-6. She has right shoulder pain with the Spurling's test. The patient desires to proceed with a surgical solution.

Request for anterior cervical discectomy and fusion at C5-6 with 23-hour observation was not certified in review. Request for appeal, anterior cervical discectomy and fusion at C5-6 with 23-hour observation was also not certified in review on July 22, 2008 with rationale that the request appears to be largely based on the results of discography as the patient is clinically neurologically normal. Additionally MRI does not show a neurocompressive lesion. Discography has not been universally accepted and is fraught with a significant number of false positives. The reviewer determined that a major surgery should not be based on subjective response to one injection.

The patient was reevaluated on August 7, 2008. The report reviews The Official Disability Guidelines references to cervical surgery, with reference to "cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain." On examination, the patient has some diminished sensation and paresthesias in the thumb region with a positive Spurling sign but is primarily experiencing midline axial neck pain and pain with increased axial compression. Her motor strength is otherwise intact. Discogram showed positive concordant pain at C5-6. The patient has exhausted a reasonable amount of conservative means of treatment that could remedy her situation. This patient meets the indications for an anterior cervical discectomy and fusion per ODG.

Request for reconsideration for lumbar discogram was not certified by the carrier on August 14, 2008 with rationale that the medical records failed to document clinical examination findings or imaging results to support the request. Additionally, the intervention was noted to be not well supported by ODG.

The patient was reevaluated on October 14, 2008. She reports continuing pain of 5/10 in the neck. On examination she demonstrates diminished sensation along the thumb region with a positive Spurling sign. Neck motion and axial compression cause increased pain. Motor strength and reflexes are symmetric. Request is for a contested case hearing "because the IRO physician was negligent with his review."

Request for anterior cervical discectomy and fusion at C5-6 with 23-hour observation was not certified in review on November 19, 2008 following a peer-to-peer discussion with rationale that "nothing objectively abnormal was noted on the neurological examination of the areas concerned. No definite surgical lesion is present on imaging studies - there is no nerve root compression. The recommendation for surgery appears to be based mainly on the results of discography - a subjective test proven to be of very questionable value in evidence based literature and that is a poor basis for making such surgical recommendations." Recommendation was for the patient to be actively involved in a home exercise program or an intensive spinal rehabilitation program followed by HEP.

Request for reconsideration/appeal of anterior cervical discectomy and fusion at C5-6 with 24 hour observation was not certified in review on November 26, 2008 with rationale that the MRI of February 2007 shows a very small central C5-6 disc herniation without pressure on the spinal cord or exiting nerve roots. Decreased sensation in the thumb and index finger are noted with normal strength and reflexes. "There is no documentation in this medical record of a large disc herniation impressing the neurologic elements, and no documentation of progressive loss of function or structural cervical spine instability." It was additionally noted that the patient does not appear to have undergone EMG clarifying a true neurologic abnormality.

The provider requested an IRO on December 9, 2008.

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

The patient is recommended surgery by her provider with fusion at C5-6 based on discogram results and a Spurling's test that elicits pain in the right shoulder. As noted by the examiner of March 2008 "the records indicate negative examination findings regarding neuromuscular deficit and essentially negative x-ray and MRI studies of the spine and shoulder." The extremity complaints are non-specific and do not correlate with abnormal x-ray or MRI findings or objective physical examination findings.

ODG state that 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. The medical records fail to document instability or progressive neurologic dysfunction that would indicate need for consideration of a fusion procedure in this patient.

ODG state discectomy and laminectomy are indicated for patients who have progression of myelopathy or focal motor deficit, intractable radicular pain in the presence of documented clinical and radiographic findings, or presence of spinal instability when performed in conjunction with stabilization, conditions not documented for this patient. The medical records fail to document clinical examination findings of progressive myelopathy or focal motor deficit or intractable radicular pain with corroborative imaging findings of a clear lesion that would warrant a consideration for the requested surgical intervention. Electrodiagnostic studies to clarify radiculopathy would have been useful. The requested intervention cannot be recommended as the best treatment plan for this patient. Therefore, my recommendation is to agree with the previous non-certification of the request for anterior cervical discectomy and fusion at C5-6 with 23-hour observation.

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 - Cervical fusion - 12-3-2008:

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. (W ieser, 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. (W ang, 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 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. (Peolsson, 2006) (Peolsson, 2003) 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 Official Disability Guidelines: Discectomy -Laminextomy - Laminoplasty

Recommended as an option if there is a radiographically demonstrated abnormality to support clinical findings consistent with one of the following: (1) Progression of myelopathy or focal motor deficit; (2) Intractable radicular pain in the presence of documented clinical and radiographic findings; or (3) Presence of spinal instability when performed in conjunction with stabilization. (See Fusion, anterior cervical.) Surgery is not recommended for disc herniation in a patient with non-specific symptoms and no physical signs. The American Academy of Orthopaedic Surgeons has recommended that an anterior approach is appropriate when there is evidence of radiculopathy, and/or when there is evidence of central location and there is any degree of segmental kyphosis. A posterior approach has been suggested by the same group when there is evidence of lateral soft disc herniations with predominate arm pain and for caudal lesions in large, short-necked individuals. (Albert, 1999) The overall goals of cervical surgery should be decompression, restoration of alignment, and stability. (Jacobs-Cochrane, 2004) (Dowd, 1999) (Colorado, 2001) In terms of posterior procedures, there does not appear to be sufficient evidence to support the use of laminoplasty versus laminectomy based on outcomes or post-operative morbidity. Research has indicated that as many as 60% of patients who received laminoplasty had posterior neck and shoulder girdle pain post-operatively (versus 25% in the laminectomy group). (Hosono, 1996) (Heller, 2001) Some authors continue to prefer laminoplasty to anterior spinal decompression and fusion (for myelopathy due to disc herniation) as they feel the risk of chronic neck pain is less troublesome than the risk of bone graft complications and/or adjacent spondylosis that can be found with the fusion procedure. (Sakaura, 2005) It is not clear from the evidence that long-term outcomes are improved with the surgical treatment of cervical radiculopathy compared with nonoperative measures. However, relatively rapid and substantial relief of pain and impairment in the short term (6-12 weeks after surgery) after surgical treatment appears to have been reliably achieved. (Haldeman, 2008)
Late deterioration: Has been found with both anterior and posterior approaches. (Rao, 2006) With the anterior approach, recurrent symptoms have been found secondary to deterioration of the adjacent segment, inadequate decompression at the time of the initial surgery, pseudoarthrosis, graft or implant failure, and/or continued growth of osteophytes. W ith the posterior approach, recurrent symptoms have been found secondary to development of kyphosis, instability, spread of ossification of the posterior longitudinal ligament, and development of stenosis at new levels. 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)
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. See Electromyography.
ODG Indications for Surgeryä -- 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 EMG requirement):
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