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Notice of Independent Review Decision

DATE OF REVIEW: 03/22/2010

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

ACDF C5-6 and C6-7 with a two-day inpatient hospital stay, 63081, 63082, 22585, 22851 (2), 22845, 20931, 95920

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 01-08-08 Cervical spine MRI read by Dr.
- o 11-25-08 Orthopedic Evaluation report from Dr.
- o 12-15-08 Electrodiagnostic study interpreted by Dr.
- o 12-17-08 Epidurography, left selective nerve root block report from Dr.
- o 12-23-08 Reevaluation report from Dr.
- o 01-12-09 Initial chiropractic evaluation report from Dr., DC
- o 02-04-09 Follow-up report from Dr.
- o 02-10-09 Follow-up report from Dr.
- o 02-12-09 Follow-up report from Dr.
- o 02-17-09 Follow-up report from Dr.
- o 02-19-09 Follow-up report from Dr.
- o 02-25-09 Follow-up report from Dr. 6/6 certified visit with ROM evaluation by Dr.
- o 09-08-09 Follow-up report from Dr. with request for ADR
- o 09-17-09 Behavioral Medicine Evaluation from xxxx
- o 10-07-09 Medical Review Report from
- o 01-29-10 Fax note from
- o 02-02-10 Follow-up report from Dr.
- o 02-11-10 Peer Review Report fromxxxxx
- o 02-15-10 Adverse Determination letter from xxxxxx
- o 03-02-10 Peer Review report fromxxxxx - reconsideration
- o 03-02-10 Adverse Determination Letter from xxxxxx - reconsideration
- o 03-05-10 Request for IRO from the claimant
- o 03-05-10 Confirmation of Receipt of Request for IRO from TDI
- o 03-08-10 Notice of Case Assignment for IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews the patient is a female who sustained an industrial injury to the cervical spine on September 4, 2008 when her exercise ball seat broke while she was keyboarding. She developed neck and arm pain with numbness and tingling in the left middle finger and weakness.

MRI performed November 8, 2008 was given impression: 1. Severe leftward foraminal stenosis at C6-7 secondary to left foraminal mixed annular protrusion and posterolateral spurring. Clinical correlation regarding evidence of left C7 radiculopathy is recommended. 2. Prominent left-sided uncovertebral spurring at C5-6 producing moderate leftward ventral cord surface flattening but no intrinsic cord signal change. There is moderate left and mild right foraminal stenosis at this level with mild central canal stenosis. 3. Mild central stenosis also noted at C4-5 and C6-7. 4. Moderate-severe right foraminal stenosis at C6-7 related to foraminal spurring. Moderate left and mild right foraminal stenosis at C5-6. 5. Mild leftward ventral cord surface flattening at C4-5, without intrinsic cord signal change, secondary to left paracentral annular protrusion and associated spurring. 6. No acute cervical spine injuries were identified.

The patient was evaluated on November 25, 2008 for left-sided neck and arm pain. She reports neck and arm pain of several months duration and numbness and tingling into the middle finger of her left hand with some weakness. She has attended PT and used ibuprofen and feels she has plateaued. She is 5' 5" and 130 pounds. Cervical range of motion is good. She can flex to the chin and extend to 40 degrees and rotate left and right to 85 degrees. There is left-sided trapezius tenderness. Motor strength is 5/5 in all muscle groups with exception of triceps which is 4/5 and half a grade weakness of her pronator muscles. Sensation is decreased in the volar aspect of the middle finger of the left hand as well as the ulnar aspect of the hand and distal forearm. X-rays taken this visit show no significant degenerative changes in the uncovertebral joints. Flexion/extension views show normal C1-2 interval and a capacious spinal canal. No instability is seen. There is mild to moderate degenerative changes C5-6 and C6-7 with 20% decrease in height and small anterior osteophytes. Cervical MRI of November 8, 2008 showed multilevel spondylosis. At C6-7 there is significant left-sided disc osteophyte complex that causes torsion of the cord, and definitely affects the C7 exiting nerve root. The patient has clinical signs of triceps and pronator weakness indicating both C6 and C7 nerve root involvement, which is consistent with disease at both C5 and C6. Recommendation is for left C6 nerve root block and nerve studies. A two level surgery may be needed of an arthroplasty to save the C4-5 level which also shows some beginning signs of disease. If a fusion is the only acceptable option, a three-level fusion would likely be recommended.

Electrodiagnostic studies were performed on December 15, 2008 and interpreted to show mild left C7 radiculopathy and no evidence for a distal, left upper extremity neuropathy.

The patient underwent epidural injection on December 17, 2008. Response to this injection was noted on December 23, 2008 to indicate C6 nerve root involvement. Some benefit was reported with the injection and an urgent need for a surgery was not indicated. On December 23, 2008 she was started on other treatments such as Mobic and she would be sent for 6-8 weeks of chiropractic care.

The patient was evaluated in chiropractic on January 12, 2009 for neck pain of 6/10 that radiates into the left arm and hand. Coughing and sneezing increase her pain. Medication and PT have not provided significant benefit. She has not smoked for 2.5 years. Hypoesthesia is noted in the left C6 and C7 dermatomes. Motor strength is full. Reflexes are symmetric. Flexion is to 38 degrees and extension to 38 degrees. Her pain pattern is elicited with cervical compression. First option was to provide 6 sessions of spinal axial decompression treatment. If not allowed, manipulative treatment with physiotherapy would be provided. A program of decompression traction was initiated on February 4, 2009.

At the 6th session of spinal decompression on February 25, 2009 the provider noted objective evidence of improvement and recommended an additional course of decompression treatment. Cervical flexion was to 54 degrees and extension to 68 degrees. Lateral flexion and rotation were improved 19 degrees.

Per the primary provider on September 8 2009, the patient was helped by an initial 20 sessions of chiropractic treatment. Her symptoms recurred with cessation of the treatment but then did not abate with re-initiation of 5 additional treatments. The patient was recommended a surgery with decompression discectomy and reconstruction of the spine with artificial disc replacement.

The patient was provided a behavioral medicine evaluation on September 17, 2009. She reported a pain level of 2/10 that on occasion increases to 7-8/10. She is working full time and feels completely worn out at the end of the work-day. She reports good quality sleep. She has a positive relationship with the employer and co-workers. She is psychologically cleared for a disc replacement surgery. Random drug screens are recommended due to high SOAPP score and elevation on substance abuse scale of MMPI-RF. The only medication noted was Darvocet; the patient had picked up the prescription the day prior and stated she had not taken any yet.

Request for artificial disc replacement surgery was considered in review on October 7, 2009 with recommendation for non-certification. Per the reviewer, the patient is not using medication and does not perform any home-exercise programs. Her physical examination shows full cervical ROM and slight restriction of left shoulder ROM on extension and internal rotation. Nerve studies suggest mild left C7 radiculopathy. Artificial disc replacement is still under study per ODG. Nerve studies note a mild C7 radiculopathy. A two-level disc replacement is not currently supported. At the current time, cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. The request was subsequently submitted in a modified form for a one level disc replacement surgery but was also not certified in review.

The patient was most recently reevaluated on February 2, 2010. Recommendation is for a two-level cervical surgery with anterior discectomy and fusion C5-6 and C6-7. EMG has shown radiculopathy at C7 and she has responded to a SNRB at C6 which indicates nerve root pain at that level. She continues to be symptomatic with neck and left arm pain and has failed conservative treatments. A Surgery scheduling sheet indicates that pre-op MD and psyche appointments have been made.

Request for a two-level ACDF C5-6 and C6-7 with 2-day inpatient LOS was considered in review on February 11, 2010 with

recommendation for non-certification. The surgery is described as, "vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment." A peer discussion with the provider was not realized, however, an assistant was contacted and agreed to fax additional clinical data to include MRI, x-rays and physical examination. The 11/08/08 MRI report was received but not the plain radiograph report or a current physical examination with cervical ROM evaluation performed on 02/25/09. Without additional clinical data and insight, the medical necessity is not established.

Request for reconsideration for was considered in review on March 2, 2010 with recommendation for non-certification. The surgery is described as, "vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment." Per the reviewer, a peer discussion was attempted but not realized. The patient has attended PT and used ibuprofen and feels she has plateaued. EMG showed left C7 radiculopathy. The C6 nerve root did not clearly demonstrate abnormality, but the selective nerve root block at C6 did show significant improvement in the first 2 to 3 hours, with recurrence of symptoms following the anesthetic phase. She has degenerative changes above and below C6 and C7. MRI of November 2008 showed severe foraminal stenosis at C6-7, left sided uncovertebral spurring at C5-6 and mild central canal stenosis at C5-6. Rationale for denial states, there is no recent physical examination. The claimant does not have clear evidence of radiculopathy. Whether the claimant uses nicotine is not determined in the records. The claimant is noted in the psychological evaluation to be at risk for aberrant medication usage. ODG is cited in regard to discectomy-laminectomy-laminoplasty criteria.

Request was made for an IRO.

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

Per ODG: Cervical fusion can be 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... 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... Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain.

- ODG Criteria for cervical surgery:
- 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

The patient has been reporting numbness and tingling into the middle finger of her left hand with some weakness for 16 months. She has attended PT and used ibuprofen more than a year ago felt she has plateaued. In November 2008 triceps motor strength was noted as 4/5 and pronator muscle strength was noted as half a grade weak. Sensation was decreased in the volar aspect of the middle finger of the left hand as well as the ulnar aspect of the hand and distal forearm. Per chiropractic exam of January, 2009 the patient's pain is increased with coughing and sneezing, there is hypoesthesia in the left C6 and C7 dermatomes and her pain pattern is elicited with cervical compression. She has been psychologically cleared for a surgery. EMG has shown radiculopathy at C7 and she has responded to a SNRB at C6 which indicates nerve root pain at that level. MRI of November 2008 showed severe foraminal stenosis at C6-7, left sided uncovertebral spurring at C5-6 and mild central canal stenosis at C5-6. Given the positive EMG findings, response to SNRB, imaging findings and duration of signs and symptoms, the surgery should be allowed. The examinations have been consistent over the past 16 months and medication issues do not appear to be present as the patient is using only Darvocet or no medication.

Therefore, recommendation is to disagree with the prior non-certification for ACDF C5-6 and C6-7 with a two-day inpatient hospital stay, 63081, 63082, 22585, 22851 (2), 22845, 20931, 95920.

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

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 (01-21-10) Neck and Upper Back Chapter - ACDF:

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.

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. Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages.

Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. 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.

One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments.

(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.

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).

(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.

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. The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation.

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.

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.

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. Patients who smoke have compromised fusion outcomes.

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. 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).

ODG (01-21-2010) Cervical - Discectomy:

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.

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 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. 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.