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Notice of Independent Review Decision

DATE OF REVIEW: 2/23/12

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of an ACDF with instrumentation at C4-C5-C6-C7 with a 1 day inpatient length of stay.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

REVIEW OUTCOME

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

- Upheld (Agree)
 Overturned (Disagree)
 Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of an ACDF with instrumentation at C4-C5-C6-C7 with a 1 day inpatient length of stay.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties: the injured worker and.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from 1/14/11 to 11/21/11 office notes by and 11/23/10 right shoulder MRI report.

1/23/12 denial letter, 11/29/11 denial letter, 12/7/10 to 11/1/11 office and consultation notes by 11/2/11 MRI scan review, 7/13/11 neurodiagnostic report,

6/24/11 cervical MRI report, 6/17/11 handwritten note from 9/23/11 to 10/7/11 individual psych notes, 11/5/10 initial patient eval psych reassessment 1/13/12, re-exam 11/23/11, 11/23/11, American Shoulder and Elbow Surgeons Eval form 11/23/11, 11/23/11 NDI form, undated surgery checklist, and undated expected surgery codes.

Argus: 8/12/11 psychological eval by

Injured worker: 11/10/10 re-exam by

11/1/10 supervisor report of injury form, 10/31/10 disability certificate by discharge instructions, various DWC 73 forms, 11/2/10 script by 11/19/10 denial of 11/23/10 lumbar MRI report, 2/14/11 IRO decision, 4/16/11 PT script, 6/23/11 DD report by with DWC 69, 7/13/11 no work script, 6/29/11 authorization letter, and undated clinical psychological evaluations (x2) by Alivio Rehab.

office notes by 11/24/10 to 1/19/11, and a procedure note 1/12/11.

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:

The diabetic has a history of a fall, with ongoing neck pain with shoulder radiation. The claimant has had ongoing neck pain and cervical tenderness. He has is a history of prior shoulder arthroscopic surgery also. A 1/13/12 dated psychological evaluation denoted the clearance for surgery. A prior 8/12/11 dated psychosocial clearance appeared to indicate an "unknown" level of patient insight regarding the proposed surgical procedure and or patient's own condition. A 6/24/11 dated cervical MRI has revealed multiple levels of protruded discs, without specific nerve root impingement noted.

Non-operative treatment was noted to have failed (including at least one if not two ESIs). Therefore has proposed surgical intervention at two levels, as noted above. The 11/1/11 dated evaluation revealed that the claimant had ongoing cervical spondylosis. There was a positive Spurling sign, hypoactive biceps and triceps reflexes, C6, C7 paresthesias and weak shoulder abduction, elbow flexion and wrist extension. As per the AP, there were disc herniations on MRI scan. Retrolisthesis in extension at C4-5 was noted, as was retrolisthesis at C5-6, along with C6-7 osteophytes. Prior AP records denoted the failure of treatments including ESIs. Stenosis, osteophytes and functional unit collapse was noted at C5-6 and C6-7. Denial letters documented the lack of a reasonable prognosis denoted in the psychosocial screen and/or the lack of detailed documentation of failure of reasonable non-operative treatments. The 7/13/11 dated electrical studies discussed the lack of cervical radiculopathies.

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

There has not been provision of actual records of the physical therapy. The actual outcomes have not been specifically documented and provided for review (regarding these forms of reported non-operative treatment). The radiologist denoted cervical protrusions on MRI vs. the AP's impression that there are herniations. In addition, the electrical studies do not exhibit radiculopathy. The aggregate of psychosocial screens present risk factors of suboptimal insight of the patient's own condition, despite the most recent clearance being positive for proceeding. Therefore, applicable ODG criteria have not been met with regards to the lack of objective clinical and corroborating electrical findings (in light of the apparent discrepancy between the radiologist's and the AP's report) along with the lack of provision of actual PT and ESI records evidencing failure of such non-operative treatments. Due to the criteria listed not being met, the requested service is found to be not medically necessary at this time.

Reference: ODG Cervical Spine

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 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.

Anterior Cervical Fusion: 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. 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. A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. Autograft is thought to increase fusion rates with less graft collapse.

(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.

(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.

(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, gainful employment, higher preoperative NDI 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, litigation and workers' compensation. 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. (FDA MedWatch, 2008) 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).

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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)